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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 500.00

Complete if Known	
Application Number	09/965,426
Filing Date	September 27, 2001
First Named Inventor	Gary R. DelDuca et al.
Examiner Name	Jyoti Chawla
Art Unit	1761
Attorney Docket No.	247097-001106USC1

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): ____

☒ Deposit Account Deposit Account Number: 50-4181 Deposit Account Name: Nixon Peabody LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	Filing Fee ($)	Filing Small Entity Fee ($)	Search Fee ($)	Search Small Entity Fee ($)	Examination Fee ($)	Examination Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent		
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent		
Multiple dependent claims		

Total Claims ____ - 20 = Extra Claims ____ x Fee ($) ____ = Fee Paid ($) ____

Indep. Claims ____ - 3 = Extra Claims ____ x Fee ($) ____ = Fee Paid ($) ____

Multiple Dependent Claims: Fee ($) ____ Fee Paid ($) ____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets ____ - 100 = Extra Sheets ____ /50 Number of each additional 50 or fraction thereof ____ (round **up** to a whole number) x Fee ($) ____ = Fee Paid ($) ____

4. OTHER FEE(S) Fees Paid ($)

Non-English Specification, $130 fee (no small entity discount) ____

Other: x **Appeal Brief** **$500.00**

SUBMITTED BY					
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: July 13, 2007 Signature: Julie A. Burke (Julie A. Burke)

Customer No. 56356

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	09/965,426	Confirmation No. 4436
Applicant	:	Gary R. DelDuca *et al.*	
Filed	:	September 27, 2001	
Title	:	MODIFIED ATMOSPHERIC PACKAGES AND METHODS FOR MAKING THE SAME	
TC/A.U.	:	1761	
Examiner	:	Jyoti Chawla	
Docket No.	:	247097-001106USC1	

TRANSMITTAL OF APPEAL BRIEF

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Signature: Julie Ann Burke
Julie Burke

Sir:

Submitted herewith is Appellants' Appeal Brief in support of the Notice of Appeal filed on May 23, 2007. Please charge the amount of $500.00 for the fees due in connection with the filing of the Appeal Brief under 37 C.F.R. § 41.20(b)(2) to Nixon Peabody LLP's Deposit Account 50-4181 (Attorney Docket No. 247097-001106USPT). Please note that the Notice of Appeal under 37 C.F.R. § 41.20(b)(1) has been previously paid. Please charge any other fees (except the issue fee) or credit any additional fees to Deposit Account 50-4181 (Attorney Docket No. 247097-001106USPT).

Date: July 13, 2007

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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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Signature: Julie Ann Burke
Julie Burke

Dear Commissioner:

This appeal brief is filed pursuant to Appellants' appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 38-56, 76-86 and 119-168 in an Office Action dated February 23, 2007, for the above-listed application.

1. REAL PARTY IN INTEREST

The real party in interest is Pactiv Corporation, a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1900 West Field Court, Lake Forest, IL 60045.

2. RELATED APPEALS AND INTERFERENCES

This appeal is related to the appeal filed in Application No. 10/190,375. The Notice of Appeal was filed on February 6, 2007 and the corresponding appeal brief was filed on April 6, 2007. This appeal is also related to the appeal filed in Application No. 09/915,150. The Notice

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of Appeal was filed on May 8, 2007 and the corresponding appeal brief was filed on May 18, 2007. There are no other related appeals and interferences.

3. STATUS OF CLAIMS

Claims 38-56, 76-86 and 119-168 are pending and have been finally rejected. The Appellants note that dependent claims 122, 141 and 160 have been previously withdrawn but are still pending the application. It is from the final rejection of claims 38-56, 76-86 and 119-168 that this appeal is taken.

Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159 and 161-168 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,686,127 to Stockley ("Stockley") in view of U.S. Patent No. 3,459,117 to Koch ("Koch"); U.S. Patent No. 4,522,835 to Woodruff ("Woodruff"); and U.S. Patent No. 6,042,859 to Shaklai ("Shaklai"). Claims 39, 77, 120, 139 and 158 stand rejected over Stockley in view of Koch, Woodruff, Shaklai and U.S. Patent No. 5,629,060 to Garwood ("Garwood").

4. STATUS OF AMENDMENTS

A Final Office Action was mailed on February 23, 2007. A Reply to Final Office Action Dated February 23, 2007 was filed with the Patent Office by Appellants on May 23, 2007, but no amendments were made. The Notice of Appeal was also filed in this patent application on May 23, 2007. In response, the Examiner issued an Advisory Action on June 18, 2007, in which the § 112, first paragraph, rejections were withdrawn and the § 103 rejections were maintained.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a method of manufacturing a modified atmosphere package and also to the modified atmosphere package (e.g., 110, 210, 310; FIGS. 8, 8A, 9B; page 13, line 18-page 14, line 29). The independent method claims (claims 38, 119 and 138) comprise supplying a package (e.g., 116; FIG. 8), a first layer (e.g., 121; FIG. 8; page 14, lines 1-4) having at least a portion being substantially permeable to oxygen and a second layer (e.g., 123; FIG. 8; page 14, lines 5-11) being substantially impermeable to oxygen. A retail cut of raw meat (e.g., 126; FIG. 8) is placed within the package (e.g., 116; FIG. 8) and the meat (e.g., 126; FIG. 8) has meat pigment. A mixture of gases is supplied within the package (e.g., 116; FIG. 8) with the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least

one other gas to form a low oxygen environment (page 20, lines 20-21; page 4, lines 19-22; page 17, lines 21-23) so as to form carboxymyoglobin on a surface of the raw meat (e.g., 126; FIG. 8; page 10, lines 9-25-page 11, line 1). Oxygen is removed within the package (e.g., 116; FIG. 8; page 10, lines 17-30) so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat (e.g., 126; FIG. 8). The first layer (e.g., 121; FIG. 8) is sealed to the package (e.g., 116; FIG. 8; page 14, lines 5-6). The second layer (e.g., 123; FIG. 8) is sealed to at least one of the group consisting of the package (e.g., 116; FIG. 8) and the first layer (e.g., 121; FIG. 8; page 5, lines 30-32).

Independent claim 38 further recites the second layer (e.g., 123; FIG. 8) being adapted to be removed such that the second layer (e.g., 123; FIG. 8) is no longer sealed to the package (e.g., 116; FIG. 8) or the first layer (e.g., 121; FIG. 8; page 14, lines 1-4), the first layer (e.g., 121; FIG. 8; page 14, lines 1-4) remains sealed to the package (e.g., 116; FIG. 8), and wherein the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is adapted to be removable after the second layer (e.g., 123; FIG. 8; page 12, lines 2-12) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer (e.g., 121; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application). Independent claim 119 further recites opening the package (e.g., 116; FIG. 8) such that the raw meat (e.g., 126; FIG. 8) is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is adapted to be removable (e.g., page 12, lines 2-12) such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package (e.g., 116; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application). Independent claim 138 further recites opening the package (e.g., 116; FIG. 8) before retail display such that the gas mixture exits the package (e.g., 116; FIG. 8) and the carbon monoxide associated with the raw meat (e.g., 126; FIG. 8) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package (e.g., 116; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application; page 12, lines 2-12).

The independent modified atmosphere package claims (claims 76 and 157) comprise a package (e.g., 116; FIG. 8) being configured and sized to fully enclose a retail cut of raw meat (e.g., 126; FIG. 8), a first layer (e.g., 121; FIG. 8; page 14, lines 1-4) and a second layer (e.g.,

123; FIG. 8; page 14, lines 5-11). The meat (e.g., 126; FIG. 8) has meat pigment and the package (e.g., 116; FIG. 8) has a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment (e.g., page 20, lines 20-21; page 4, lines 19-22; page 17, lines 21-23) so as to form carboxymyoglobin on a surface of the raw meat (e.g., 116; FIG. 8). The first layer (e.g., 121; FIG. 8; page 14, lines 1-4) has at least a portion being substantially permeable to oxygen and sealed to the package (e.g., 116; FIG. 8). The second layer (e.g., 123; FIG. 8; page 14, lines 5-11) is substantially impermeable to oxygen and sealed to at least one of the group consisting of the package (e.g., 116; FIG. 8) and the first layer (e.g., 121; FIG. 8; page 5, lines 30-32; page 14, lines 1-4).

Independent claim 76 further recites the second layer (e.g., 123; FIG. 8; page 14, lines 5-11) being adapted to be removed such that the second layer (e.g., 123; FIG. 8) is no longer sealed to the package (e.g., 116; FIG. 8) or the first layer (e.g., 121; FIG. 8; page 14, lines 1-4), and the first layer (e.g., 121; FIG. 8; page 14, lines 1-4) remains sealed to the package (e.g., 116; FIG. 8), and wherein the carbon monoxide associated with the raw meat (e.g., 116; FIG. 8) is adapted to be removable after the second layer (e.g., 121; FIG. 8; page 14, lines 1-4) is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer (e.g., 123; FIG. 8; page 14, lines 1-4; page 12, lines 2-11, page 21, lines 20-29; examples of the present application). Independent claim 157 further recites wherein the package (e.g., 110; FIG. 8) is adapted to be opened such that the raw meat (e.g., 116; FIG. 8) is allowed to be exposed to the ambient atmosphere and wherein the carbon monoxide associated with the raw meat (e.g., 116; FIG. 8) is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package (e.g., 110; FIG. 8; page 14, lines 1-4; page 12, lines 2-11; page 21, lines 20-29; examples of the present application).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 38, 40-56, 76, 78-86, 119, 121, 123-138, 140, 142-157, 159 and 161-168 stand rejected under 35 U.S.C. § 103 as being obvious over U.S. Patent No. 5,686,127 to Stockley in view of U.S. Patent No. 3,459,117 to Koch; U.S. Patent No. 4,522,835 to Woodruff;

U.S. Patent No. 6,042,859 to Shaklai and dependent claims 39, 77, 120, 139 and 158 are further rejected under § 103 in view of U.S. Patent No. 5,629,060 to Garwood.

7. ARGUMENT

The Appellants will discuss (1) the present invention, (2) the general case law of obviousness, (3) the reasons why a *prima facie* case has not been satisfied by the obviousness rejections and (4) additional evidence on why the pending claims are not obvious. To assist in explaining the present invention and showing the non-obviousness of the invention, the Appellants previously submitted evidence in the form of several 37 C.F.R. §1.132 declarations by (a) one of the co-inventors Mr. Gary R. DelDuca (Exhibits 1-4)[1]; and (b) one skilled in the art of meat processing using modified atmosphere packaging -- Dr. Melvin C. Hunt ("the Hunt Declaration")[2] (Exhibit 5).

I. Present Invention

The modified atmosphere packages and the methods of manufacturing the same have several advantages: (a) the "seasoning" period of the raw meat may be reduced or eliminated; (b) the ability to obtain consistent blooming with cuts off pigment-sensitive meats (e.g., round bone) is improved; and (c) the ability to avoid "fixing" the color of the meat pigment to red. See, e.g., page 11, line 29 – page 12, line 15; page 13, lines 11-17 of the application; DelDuca Decl. ¶ 4 (Exhibit 1).

The "seasoning" period is the time period needed to diffuse the oxygen so that the meat has the ability to fully bloom. Page 3, lines 17-19 of the application; DelDuca Decl. ¶ 5. Trays, such as polystyrene foam trays, have a substantial amount of oxygen contained in its cellular structure that results in a time period of as long as about 5 to about 6 days to diffuse the oxygen contained in its cellular structure. Page 3, lines 21-23 of the application; DelDuca Decl. ¶ 5. If a foam tray is not used, the "seasoning" period can be reduced to one or two days. Page 3, lines 24-25 of the application; DelDuca Decl. ¶ 5. The reduction or elimination of the seasoning

[1] The DelDuca declarations were respectfully submitted as exhibits in the Amendment and Response to Office Action Dated May 7, 2003; Amendment and Response to Office Action Dated June 14, 2004; Amendment and Response to Final Office Action Dated August 12, 2005; and Amendment and Response to Office Action Dated February 24, 2006.

[2] The Hunt Declaration was submitted in this pending application as an exhibit in the Amendment and Response to Office Action Dated June 14, 2004.

period "allows the meat to be displayed for retail sale much sooner than in existing low oxygen packaging systems." Page 11, line 29 – page 12, line 2 of the application; DelDuca Decl. ¶ 5. Seasoning periods are not desired by the retailers or packers because of the "need to store and maintain the meat-filled packages for an extended duration before being opened for retail sale." Page 3, lines 25-28 of the application; DelDuca Decl. ¶ 5.

One important aspect of the present invention is that the present invention does not "fix" the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period after removal of the second layer that is substantially impermeable to oxygen or the opening of the package. See page 12, lines 2-12 of the application; DelDuca Third Decl. ¶ 3 (Exhibit 3). It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. See DelDuca Third Decl. ¶ 3 (Exhibit 3). The term "fix" in this context does not mean that the color of meat pigment <u>never</u> changes to a brown color, but rather that the meat pigment does <u>not</u> turn brown in a natural time period after the meat pigment is exposed to atmosphere. *Id.*

The present invention "surprisingly allows the meat pigment to convert to metmyoglobin in a similar fashion as fresh, raw meat in a retail environment." Page 12, lines 7-10 of the application; DelDuca Decl. ¶ 7 (Exhibit 1). Specifically, the color of the meat pigment after exposure to ambient temperature degrades in a fashion that is not beyond the point of microbial soundness, as if the CO had never been added to the modified packaging system. *Id.*

The meat used in the modified atmosphere packaging of the present invention substantially maintains its color during the shipping process because the package has a modified atmosphere in one embodiment that includes from about 0.1% to about 0.8 vol.% carbon monoxide. See DelDuca Decl. ¶ 8. In one method, after removal of the substantially impermeable layer, the CO is lost to the atmosphere. See page 12, lines 2-6 of the application; DelDuca Decl. ¶ 8. The CO may be lost to the atmosphere through the first layer that includes a portion that is substantially permeable to oxygen. *Id.* This allows the conversion of the carboxymyoglobin to oxymyoglobin by using the oxygen from the air. *Id.* The "gas mixture used in the modified atmosphere packages of the present invention, after removal, allows the

carboxymyogolobin to convert to oxymyoglobin and then to metymyoglobin (brown) in a natural time period." *Id.*

II. General Law on Obviousness

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct 1727 (2007) stated that the teaching, suggestion and motivation test is not to be rigidly applied, but did not apply a specific test to determine obviousness. Applying the *KSR Int'l* decision, the Federal Circuit in *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc.* stated that "[a]n obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case." 485 F.3d 1157, 1161 (Fed. Cir. 2007). Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. *See KSR Int'l Co. v. Teleflex Inc.* 127 S.Ct. at 1741.

Prior to the *KSR Int'l Co.* decision, the teaching, suggestion and motivation test stated that all the limitations of a claim must be taught or suggested by the combined prior art references. M.P.E.P. § 2143.03 (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974)). A *prima facie* case of obviousness requires three basic criteria:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P. § 2143.

Obviousness cannot "be established using hindsight or in view of the teachings or suggestions of the invention." *Ex parte Maguire*, No. 1999-1344, 2002 WL 1801466, at *4 (Bd. Pat. App. & Inter. 2002) (quoting *Para-Ordnance Mfg. Inc. v. SGS Importers Int'l Inc.*, 73 F.3d 1085, 1087, 37 U.S.P.Q.2d 1237, 1239 (Fed. Cir. 1995), *cert. denied*, 519 U.S. 822 (1996)). Further, the proposed modification cannot render the prior art "unsatisfactory for its intended purpose" nor can it "change the principle of operation" of a reference. M.P.E.P. § 2143.01 (citing *In re Gordon*, 733 F.2d at 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984), and *In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959)).

The law of obviousness requires that a reference be considered as a whole, including those portions that teach away from the claimed invention. *Armament Sys. & Procedures v.*

Monadnock Lifetime Prods., No. 97-1174, 1998 U.S. App. LEXIS 20818, at *23-24 (Fed. Cir. 1998); see also M.P.E.P. § 2141.02 (stating that prior art must be considered in its entirety including disclosures that teach away from the claims). Indicia of teaching away in a reference give insight into the question of obviousness. *Monarch Knitting Mach. Corp. v. Sulzer Morat GMBH,* 139 F.3d 877, 885, 45 U.S.P.Q.2d 1977, 1984 (Fed. Cir. 1998). A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *Id.* (quoting *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994)).

The Examiner, of course, has the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention under any statutory provision. *In re Mayne*, 104 F.3d 1339, 1341, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

For at least the reasons stated below, Appellants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness under 35 U.S.C. § 103 and requests reversal of the Examiner's 35 U.S.C. § 103 rejections.

III. A *Prima Facie* Case Has Not Been Presented With Respect To Independent Claims 38, 76, 119, 138 and 157

The pending independent claims (claims 38, 76, 119, 138 and 157) include, *inter alia*, (a) "a first layer having at least a portion being substantially permeable to oxygen"; (b) "a second layer being substantially impermeable to oxygen"; (c) a low oxygen environment that includes from about 0.1 to about 0.8 vol.% CO; (d) the second layer being sealed to the package or the first layer, and (e) "wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer"; "opening the package such that the raw meat is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package" or "opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the

package." None of the applied references includes, *inter alia*, such limitations that are recited in independent claims 38, 76, 119, 138 and 157.

As acknowledged by the Examiner, U.S. Patent No. 5,686,127 to Stockley does not disclose, teach or suggest the use of CO. See page 3 of the Office Action dated August 12, 2005. The Examiner applies a number of references – Woodruff, Koch and Shaklai in an attempt to cure this deficiency in Stockley. These other references do not disclose a packaging system having, *inter alia*, (a) "a first layer having at least a portion being substantially permeable to oxygen"; and (b) "a second layer being substantially impermeable to oxygen" as recited in independent claims 38, 76, 119, 138 and 157.

It would not have been obvious to combine Stockley in view of other references such as Koch, Woodruff and/or Shaklai to arrive at the present invention. This erroneous conclusion by the Examiner ignores the understanding of those of ordinary skill in the art at the time of the present invention that CO "fixes" the color of the meat pigment and there would be no motivation to one of ordinary skill in the art for using CO in a modified atmosphere such as disclosed in Woodruff, Koch and/or Shaklai with a meat-packaging system such as disclosed in Stockley.

A. The Problems Of "Fixing" Color Are Known To Those Of Ordinary Skill In The Art

The problems of fixing meat color with CO, which can mask spoilage, are clearly known to those of ordinary skill in the art. See, e.g., Hunt Decl. ¶ 6 (Exhibit 5); DelDuca Second Decl. ¶ 4 (Exhibit 2). The problem of fixing meat color with CO was described in a previously applied reference in this application to Sorheim et al.[3] Furthermore, the United States Food and Drug Administration (FDA) has believed that the meat pigment color would be fixed using CO.[4] Thus, the alleged "good" color (i.e., red color of fresh meat) disclosed in, for example,

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[3] The applied reference was "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide" from *Meat Science* to Sorheim et al. ("Sorheim")(Exhibit 6), which was applied in the Office Action mailed on May 7, 2003. In particular, Sorheim disclosed that its meat packaging systems with a modified atmosphere of "0.4% CO/60% CO_2/40% N_2 had a bright stable red colour that lasted beyond the time of spoilage." (Underlining added). Abstract of Sorheim.

[4] Exhibit 7 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color", which was submitted in the Amendment and Response to Office Action Dated May 7, 2003); see also Hunt Decl. ¶ 6.

Woodruff is not a desirable attribute when the meat pigment remains such a color past its microbial soundness.

Thus, there is simply no motivation to combine Stockley with Woodruff, Koch, Shaklai and/or Garwood in an attempt to address the problems solved by the present invention and to read on the pending claims.

B. The Applied References Of Shaklai, Koch, Woodruff And Garwood Do Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Based on the strong submitted evidence from the Appellants that those of ordinary skill in the art believed that CO "fixed" the color of the meat pigment at the time of the invention (i.e., that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to the atmosphere), the Examiner has attempted to apply a number of references allegedly stating otherwise. The Appellants will discuss these references and the reasons why they do not modify the belief before the Appellant's invention that CO "fixed" the color of the meat pigment.

Specifically, the Examiner states that: (a) "Shaklai and Koch . . . provide evidence that the packages of Stockley . . . will have CO [being] removably associate d with the meat in a natural time period"; and (b) "the art of record does show that meat exposed to CO will brown within a natural time period after removal of CO and exposure to normal atmosphere." Page 6 of the Office Action dated August 18, 2006.

In addition to not disclosing, teaching or suggesting the claimed first and second layers in the modified atmosphere package, none of the references of Shaklai, Koch or Woodruff, which are individually discussed in detail below, teaches or suggests any of the claimed limitations of (a) "wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer"; (b) "opening the package such that the raw meat is allowed to be exposed to the ambient atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package" or (c) "opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package." One of these

limitations is specifically recited in independent claims 38, 76, 119, 138 and 157. Thus, there is no motivation to combine Shaklai, Koch and/or Woodruff with Stockley in the pending rejections.

i. Shaklai Teaches That CO "Fixes" The Color Of The Meat Pigment (I.e., Extends Color Life)

Since Shaklai teaches that CO "fixes" the color of the meat pigment after exposure to the atmosphere, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Carr, Koch and Woodruff as in the pending rejections.

Specifically, Shaklai discloses exposing raw meat to an atmosphere consisting essentially of CO in which the meat is "completely immersed or saturated" with CO. See col. 5, lines 29-37. "More specifically, a cross-section of meat is completely immersed in or saturated to its core with carbon monoxide from the exposed surfaces through the entire cross-section (thickness) including its core region and retains the carbon monoxide until the meat is cooked. Thus, as stated above, the meat is preserved throughout its thickness." Col. 5, lines 38-43 of Shaklai.

Shaklai continues by stating that "[p]ractically all of the carbon monoxide (over 99.9%) taken up by meat will be maintained as hemoglobin and myoglobin (Hb/Mb) bound forms." Col. 5, lines 57-59. Shaklai also discloses that "[b]oth hemoglobin and myoglobin bind carbon monoxide much more strongly than oxygen." Col. 5, lines 66-67. "It is thought that the mechanism for carbon monoxide preserving of meat is the much greater affinity of myoglobin for carbon monoxide than for oxygen." Col. 6, lines 26-28 of Shaklai.

It is known to those of ordinary skill in the art that when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity <u>200</u> times greater than oxygen does with hemoglobin.[5] Therefore, one of ordinary skill in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. DelDuca Third Decl. ¶ 4 (Exhibit 3). In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Appellants' invention, would not have been expected to degrade in a natural time period. *Id.*

The examples of Shaklai also support that the meat pigment is "fixed" beyond its natural time period. Specifically, Example 4 of Shaklai (mentioned at page 7 of the Office Action dated

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[5] See, e.g., Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979 (Exhibit 8) submitted in Amendment and Reply to Final Office Action dated August 12, 2005; DelDuca Third Decl. ¶ 4 (Exhibit 3).

February 24, 2006) discloses that (a) meat treated with CO on day 14 had only a surface (less than 1 mm deep) being brown, while (b) meat treated with air was dark brown throughout. Col. 9, lines 40-50. Thus, it is clear that the meat pigment in Example 4 was "fixed" because it extended the color of meat pigment past its natural time period after being exposed to the atmosphere. This is further illustrated in Example 3 of Shaklai where the air-treated meat and CO-treated meat had different colors – the air-treated meat after 3 days was all brown and the CO-treated meat was a wine-red color. Col. 9, lines 10-19. Example 2 of Shaklai mentioned at page 7 of the Office Action dated February 24, 2006 also does not support that meat pigment is not "fixed" beyond its natural time period (air-treated samples were brown and CO-treated samples were a bright wine red after 24 hours). Col. 8, line 50-col. 9, line 5.

The Examiner asserts that Shaklai is being relied on as not fixing the color of the meat pigment surface. Pages 6-8 of the Office Action dated August 18, 2006; Page 7 of the Office Action dated February 24, 2006. This ignores the evidence in the above examples that Shaklai discloses that the color of the meat pigment is fixed. There is no expectation in Shaklai that by applying the CO levels disclosed in Woodruff that the meat would brown in a natural time period, let alone the "reasonable expectation of success" asserted by the Examiner. See page 6 of the Office Action dated August 18, 2006.

Thus, because Shaklai discloses "fixing" the color of the meat pigment, there would be no motivation to one of ordinary skill in the art to combine Shaklai with Stockley, Koch and Woodruff as in the pending rejections because Shaklai discloses "fixing" the color of the meat pigment.

ii. Koch Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of its CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai and Woodruff as in the pending rejections.

Specifically, Koch discloses wrapping meat with a CO-containing film such that CO is transferred from the film to contact the surface of the meat. See abstract. An object of Koch is to include a relatively <u>small quantity of CO</u> that is gradually released from the CO-containing film. Col. 2, lines 18-22. Koch discloses (a) covering primal cuts made at a slaughterhouse with

a CO-containing film, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc. Col. 3, lines 4-8.

First, Koch does not disclose the exact weight of the primal cuts of meat. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. DelDuca Third Decl. ¶ 7 (Exhibit 3). The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. *Id.* Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat. *Id.*

Second, the disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. See col. 9, lines 11-28 of Shaklai and DelDuca Third Decl. ¶ 8. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-surface meat pigments to carboxymyoglobin. *Id.*

Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film. *Id.* It would be expected that the individually cut steaks and roasts sections of Koch that were <u>not</u> exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also <u>not</u> been exposed to CO. DelDuca Third Decl. ¶ 9. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts <u>not</u> exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. *Id.* Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film. *Id.*

In response to these arguments, the Examiner states that "Koch . . . each the use of their package for primal as well as the final cuts" and concludes that the "CO [is] removably associated with the meat in a natural time period." Page 8 of the Office Action dated August 18, 2006. This ignores the primal cuts to which Koch is directed, in which individual steaks and roast sections are not exposed to CO. Koch discloses "[w]hen the <u>primal cuts</u> arrive at the retail outlet, the covers are removed and the meat is cut into individual steaks, roasts, etc. which may be separately wrapped in conventional wrapping materials. It has been found that meat will

release a saleable red color for as long as 10 days when covered with the cover herein described for the first seven days and with a conventional cover for the remaining days." Col. 3, lines 5-13 of Koch (underlining added); DelDuca Fourth Decl. ¶ 15 (Exhibit 4).

In summary, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film because it would not be reasonable that exposing a relatively small quantity of CO that is gradually released from the CO-containing film to a large quantity of meat (primal cuts) would expose CO to the non-surface meat pigments.

Since Koch does not teach or suggest that the use of CO turns meat pigment brown in a natural time period after removal of the CO-containing film, there would be no motivation to one of ordinary skill in the art to combine Koch with Stockley, Shaklai and Woodruff as in the pending rejections.

iii. Woodruff Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

The Examiner states that Woodruff "teach[es] that CO concentrations in the recited range of the applicant have been known to provide good color in meat during transportation and storage." Page 5 of the Office Action dated August 18, 2006. The Examiner continues by stating that "Woodruff [] teaches surface contact of a meat with CO to maintain a red color". *Id.* at page 6.

Woodruff does not teach or suggest that the color of the meat pigment turns brown in a natural time period. DelDuca Fourth Decl. ¶ 12 (Exhibit 4). For example, Woodruff in Example 1 discloses a 0.5 lb. beefsteak that was exposed to 0.5% CO, which was nearly all absorbed two days later. See col. 4, lines 34-48; DelDuca Fourth Decl. ¶ 12. After being exposed in a modified atmosphere that included 16% oxygen, "the beefsteak retained its good red color, and the carboxymyoglobin color had penetrated no more deeply than it had at the end of the two days." See col. 4, lines 49-54. This passage implies that the carboxymyoglobin color was still retained within the beefsteak after 6 days despite being exposed to an atmosphere with a generally similar amount of oxygen as in air (compare about 21% oxygen to 16% oxygen). DelDuca Fourth Decl. ¶ 12. It would be expected to one skilled in the art that the beefsteak would turn brown in about 2-3 days, depending on the cut of meat. *Id.* Thus, this example clearly shows that the beefsteak of Woodruff in Example 1 did not turn brown in a natural time

period, but rather "fixed" the color of the meat pigment. *Id.* Similarly, in Example 1 of Woodruff, a 0.5 lb. beefsteak exposed to 2.5% CO under similar conditions also retained its good color after 6 days. See col. 4, line 55- col. 5, line 6; DelDuca Fourth Decl. ¶ 12.

None of the other examples of Woodruff supports a modified atmosphere package wherein the CO associated with the raw meat is adapted to be removed such that the color of the meat pigment is not fixed and turns brown in a natural time period. DelDuca Fourth Decl. at ¶ 13. Rather, the other examples of Woodruff generally disclose the condition of the meat pigment while being stored in a modified atmosphere containing CO. *Id.* In summary, Woodruff does not disclose, teach or suggest that the use of CO on meat pigment turns brown in a natural time period, but rather Woodruff teaches and suggests "fixing" the color of the meat pigment in Example 1. *Id.* at 14.

Since Woodruff does not teach or suggest that the use of CO turns meat pigment brown in a natural time period, there would be no motivation to one of ordinary skill in the art to combine Woodruff with Stockley, Shaklai and Koch as in the pending rejections.

iv. Garwood Does Not Teach Or Suggest That The Use Of CO Turns Meat Pigment Brown In A Natural Time Period

The other applied reference (Garwood) has not been applied for teaching that the use of CO turns meat pigment brown in a natural time period. See, e.g., pages 6-7 of the Office Action dated August 18, 2006. Thus, the Appellants believe that a *prima facie* case has not been presented with Stockley, Woodruff, Koch, Shaklai, Garwood or any combination thereof.

IV. Evidence of Non-Obviousness of Independent Claims 38, 76, 119, 138 and 157

Assuming, *arguendo*, that a *prima facie* case has been presented (which Appellants strongly believe is not the case), the Appellants previously submitted evidence of non-obviousness including the DelDuca Declarations (Exhibits 1-4) and the Hunt Declaration (Exhibit 5). Secondary consideration such as long felt but unsolved needs, failure of others, etc. may be used to give light to the circumstances surrounding the origin of the subject and, thus, may be used to rebut a *prima facie* case of obviousness. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).

A. CO Not Allowed With Fresh Meat In The United States Since At Least 1962

Carbon monoxide (CO) has not been allowed to be used with fresh meat in the United States for about 40 years.[6,7] The Food and Drug Administration ("FDA") regulation that currently prevents using CO with meat-packaging systems in the United States is 21 C.F.R. § 173.350.

> The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen...(b) The food additive meets the following specifications: (1) Carbon monoxide content not to exceed 4.5 percent by volume...(c) It [carbon monoxide] is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, <u>except fresh meats</u>.

Exhibit 11 (emphasis added); see also DelDuca Decl. ¶ 9 (Exhibit 1).

The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is unsafe and potentially dangerous to consume because it has unacceptable levels of bacteria. DelDuca Decl. ¶ 10 (Exhibit 1).[8] This act of fixing the meat color to a bright red color is referred to as "economic adulteration." *Id.*

B. CO Now Allowed In Pactiv's Novel Approaches

After about 40 years of not allowing CO to be used with fresh meats in the United States, the Appellants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of "fixing" the meat color. DelDuca Second Decl. ¶ 4 (Exhibit 2).

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[6] 21 U.S.C. § 121.1060 was first promulgated on August 2, 1961 (Exhibit 9) and permitted the use of combustion product gas containing up to 4.5% CO for use "to displace or remove oxygen or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, and wine." In December 14, 1962, 21 U.S.C. § 121.1060 (Exhibit 10) was amended to <u>exclude fresh meats</u>. In March of 1977, 21 U.S.C. § 121.1060 was re-designated as 21 C.F.R. § 173.350. Both Exhibits 9 and 10 were submitted in the Amendment and Response to Office Action Dated May 7, 2003.

[7] See also DelDuca Decl.¶ 9.

[8] See, e.g., Exhibit 7 (In a 1962 letter, the FDA told a Whirlpool representative that it might need additional data "to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated" and that the FDA has a question "concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color.")

i. One Novel Pactiv Approach[9]

One of the novel approaches invented by the Appellants that avoids the concerns of fixing the color of the meat pigment involved using a specific MAP system that was presented in a GRAS notice ("Pactiv's improved ActiveTech® meat packaging system"). Pactiv's improved ActiveTech® meat packaging system included meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride ("PVC") overwraps. DelDuca Second Decl. ¶ 5. The wrapped trays of meat are then placed in an outer barrier bag. *Id.* Ambient air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide, and the balance being nitrogen. *Id.*

Dr. Hunt, who has extensive experience in the processing of meat using modified atmosphere packaging, stated that "[t]he results of the testing [of the Pactiv's improved ctiveTech® meat packaging system] were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red." Hunt Decl. ¶ 6 (Exhibit 5). Pactiv's improved ActiveTech® meat packaging system using 0.4 vol.%, however, did not fix the color of the meat pigment as expected and Dr. Hunt stated that "[t]his was a novel result and was not at all obvious due to the current and long standing thought that meat exposed to CO would develop a color that would mask spoilage." *Id.*

The FDA stated that it had no questions regarding Pactiv's conclusion about Pactiv's improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its GRAS notice. DelDuca Second Decl. ¶ 6 (Exhibit 2); Exhibit 12[10]. This FDA review allows Pactiv to use CO with fresh meat in its application. *Id.* It is believed to be the first system to overcome the prohibition of CO with fresh meat in the United States in the last 40 years. *Id.*

ii. Another Novel Pactiv Approach

Besides Pactiv's improved ActiveTech® meat packaging system, the Appellants invented other novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoid the concerns of "fixing" the meat color. Some of these other novel approaches include low oxygen environment, meat packaging systems having (a) a first layer being a substantially

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9 This novel approach is the subject of other patent applications.

10 Exhibit 12 was originally submitted as an exhibit to the DelDuca Second Declaration, which was filed in the Amendment & Reply to Office Action Dated June 14, 2004.

permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture including 0.4 vol.% CO.

An example of a low oxygen environment, meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. DelDuca Second Decl. ¶ 8 (Exhibit 2). A peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. *Id.* The first layer is located closest to the meat, while the second layer is located farthest from the meat. *Id.* The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the substantially permeable first layer. *Id.*

The process of manufacturing the above-described peelable system is one example of a process that would be covered by independent claims 38, 119 and 138 of the present application. *Id.* at ¶ 9. The above-described peelable system is one example of modified atmosphere packaging that would be covered by independent claims 76 and 157 of the present application. *Id.*

It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. DelDuca Second Decl. ¶ 9; Hunt Decl. ¶ ¶ 7-9. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap). DelDuca Second Decl. ¶ 9; Hunt Decl. ¶ 9.

Cryovac makes such a peelable system using 0.4 vol.% CO under the name Darfresh®. DelDuca Second Decl. ¶ 11. Cryovac in its GRAS notice represented that the Cryovac package "allow[s] the meat pigment color to change over time as though it has not been exposed to CO." *See* DelDuca Second Decl. ¶ 11; Exhibit 13[11]. As a result, the "FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 00083 [which is directed to Pactiv's improved ActiveTech® meat packaging system] ." *Id.* Thus, both Cryovac and the FDA believe that such a peelable system using 0.4 vol.% CO would not fix the color of the meat pigment to red.

[11] Exhibit 13 was originally submitted as an exhibit to the DelDuca Second Declaration, which was filed in the Amendment & Reply to Office Action Dated June 14, 2004.

Dr. Hunt also stated that he believed "that the surprising results obtained in the testing of Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO would be equally applicable" to methods such as the peelable system described above. Hunt Decl. ¶ 7.

Thus, a problem of fixing meat color with CO that was recognized for at least the last 40 years was overcome by various inventive embodiments/methods of the Appellants including (a) Pactiv's improved ActiveTech® meat packaging system and process of manufacturing the same; and (b) a peelable meat packaging system described above and process of manufacturing the same, which is an example of a system and a process that would be covered by the independent claims of the present application. Additionally, such results were surprising to one skilled in the art (Dr. Hunt) in that they did not fix the color of the meat pigment to red.

C. Pactiv's Novel Meat-Packaging Systems and Processes Using CO Address a Long-Felt Need

The Federal Circuit has stated that if an invention unexpectedly solved longstanding problems, it supports the conclusion of nonobviousness. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1382 (Fed. Cir 1986); *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

Pactiv's novel meat-packaging systems and methods of manufacturing the same are examples of systems and processes that addressed such a long-felt need. More specifically, both (a) Pactiv's improved ActiveTech® meat packaging system and (b) a peelable meat-packaging system described above and process of the same, which is an example of a system and a process that would be covered be independent claims of the present application, addressed such a long-felt need in the meat-packaging industry. "Prior to Pactiv's novel meat packaging approaches using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product." *See* Hunt Decl. ¶ ¶ 10, 11. "Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations." *See id.* Pactiv's novel meat packaging systems using 0.4 vol.% CO were new and novel approaches that addressed these technological needs." *See id.*

Thus, since Pactiv's novel meat packaging systems using 0.4 vol.% CO surprisingly addressed a long-felt need, this is further evidence that the independent claims of the present application are not obvious over the applied references.

In response to this evidence on long-felt need, the Examiner asserted that "[i]t is notoriously well known in the art [from the applied references] that a red colored meat at the retail outlet is most desired. It was also known that meat exposed to CO in a modified atmosphere environment would provide the meat with a red color after the meat was removed from the modified atmosphere environment." Page 11 of the Office Action dated August 18, 2006. This clearly ignores the understanding of those skilled in the art prior to Appellant's invention that CO "fixed" the color of the meat pigment, which is discussed in detail above.

Therefore, in addition to the applied references not presenting a *prima facie* case, the Appellants also believe that the pending claims are allowable because of the compelling evidence of non-obviousness. Therefore, independent claims 38, 76, 119, 138 and 157 are not obvious in view of Stockley, Woodruff, Koch, Shaklai and Garwood or any combination thereof and, thus, should be in a condition for allowance and the Appellants request reversal of the Examiner's 35 U.S.C. § 103 rejections.

8. CONCLUSION

For the reasons set forth above, Appellants respectfully submit that the Examiner's rejections fail to present a *prima facie* case of obviousness under 35 U.S.C. § 103. Additionally, even if a *prima facie* case has been presented (which Appellants strongly believe is not the case), the overwhelming evidence of non-obviousness rebuts any *prima facie* case of obviousness. Based upon the arguments submitted above, Appellants respectfully solicit the reversal of the Examiner's 35 U.S.C. § 103 rejections of claims 38-56, 76-86 and 119-168 on at least the grounds noted above.

The Appellants note that the fee of $500.00 required by 37 C.F.R. §41.20(b)(1) has already been paid. The Appellants request that the fee of $500.00 for the Notice of Appeal filed under 37 C.F.R. §41.20(b)(2) be deducted from Nixon Peabody LLP Deposit Account No. 50-4181 (247097-001106USPT). The Commissioner is also hereby authorized to charge deposit account No. 50-4181 (Attorney Docket No. 247097-001106USPT) for any additional fees

inadvertently omitted which may be necessary now or during the pendency of this application, except for the issue fee.

July 13, 2007
Date

Respectfully submitted,

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9. RELATED PROCEEDINGS APPENDIX

None

10. APPENDIX OF CLAIMS ON APPEAL

Listing of Claims:

1-37 Cancelled.

38. A method of manufacturing a modified atmosphere package, the method comprising:

supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package; and

sealing the second layer to at least one of the group consisting of the package and the first layer, the second layer being adapted to be removed such that the second layer is no longer sealed to the package or the first layer, the first layer remains sealed to the package, and wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer.

39. The method of claim 38, wherein a pocket is formed between the first layer and the second layer.

40. The method of claim 38, wherein the second layer is at least sealed to the first layer and the second layer is adapted to be peelable from the first layer.

41. The method of claim 38, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.

42. The method of claim 38 further including removing the second layer.

43. The method of claim 38 further including supplying an oxygen scavenger.

44. The method of claim 38, wherein the oxygen level in the package is less than 1,000 ppm.

45. The method of claim 44, wherein the oxygen level in the package is less than about 500 ppm.

46. The method of claim 38, wherein removing oxygen from the package includes evacuating the package.

47. The method of claim 38, wherein removing oxygen from the package includes flushing the package with the gas mixture.

48. The method of claim 38, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.

49. The method of claim 38, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

50. The method of claim 38, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.

51. The method of claim 38 further including placing the retail cut of raw meat on a foam tray.

52. The method of claim 38, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.

53. The method of claim 38, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.

54. The method of claim 38, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.

55. The method of claim 38, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.

56. The method of claim 38, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

57-75. Cancelled.

76. A modified atmosphere package, comprising:

a package being configured and sized to fully enclose a retail cut of raw meat, the meat having meat pigment, the package having a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

a first layer having at least a portion being substantially permeable to oxygen and sealed to the package; and

a second layer being substantially impermeable to oxygen and sealed to at least one of the group consisting of the package and the first layer, the second layer being adapted to be removed such that the second layer is no longer sealed to the package or the first layer, and the first layer remains sealed to the package, and wherein the carbon monoxide associated with the raw meat is adapted to be removable after the second layer is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon removal of the second layer.

77. The package of claim 76, wherein a pocket is formed between the first layer and the second layer.

78. The package of claim 76, wherein the second layer is at least sealed to the first layer, the second layer being adapted to be peelable from the first layer.

79. The package of claim 76, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects laterally outwardly therefrom.

80. The package of claim 76 further including supplying an oxygen scavenger.

81. The package of claim 76, wherein the oxygen level in the package is less than 1,000 ppm.

82. The package of claim 81, wherein the oxygen level in the package is less than about 500 ppm.

83. The package of claim 76, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

84. The package of claim 77, wherein the package further includes a foam tray sized to hold the meat.

85. The package of claim 77, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.

86. The package of claim 77, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

87-118. Cancelled

119. A method of manufacturing a modified atmosphere package, the method comprising:

supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package;

sealing the second layer to at least one of the group consisting of the package and the first layer; and

opening the package such that the raw meat is allowed to be exposed to the ambient

atmosphere and the carbon monoxide associated with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening the package.

120. The method of claim 119, wherein a pocket is formed between the first layer and the second layer.

121. The method of claim 119, wherein the second layer is at least sealed to the first layer, the second layer being peeled from the first layer such that the raw meat is allowed to be exposed to the ambient atmosphere through the second layer.

122. The method of claim 119, wherein the second layer is at least sealed to the package and the second layer is peeled from the package such that the raw meat is allowed to be exposed to the ambient atmosphere through the second layer.

123. The method of claim 119, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.

124. The method of claim 119 further including supplying an oxygen scavenger.

125. The method of claim 119, wherein the oxygen level in the package is less than 1,000 ppm.

126. The method of claim 125, wherein the oxygen level in the package is less than about 500 ppm.

127. The method of claim 119, wherein removing oxygen from the package includes evacuating the package.

128. The method of claim 119, wherein removing oxygen from the package includes flushing the package with the gas mixture.

129. The method of claim 119, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.

130. The method of claim 119, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

131. The method of claim 119, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.

132. The method of claim 119 further including placing the retail cut of raw meat on a foam tray.

133. The method of claim 119, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.

134. The method of claim 119, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.

135. The method of claim 119, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.

136. The method of claim 119, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.

137. The method of claim 119, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

138. A method of manufacturing a modified atmosphere package, the method comprising :

supplying a package, a first layer having at least a portion being substantially permeable to oxygen and a second layer being substantially impermeable to oxygen;

placing a retail cut of raw meat within the package, the meat having meat pigment;

supplying a mixture of gases within the package, the gas mixture comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

removing oxygen within the package so as to sufficiently reduce an oxygen level therein so as to inhibit or prevent the formation of metmyoglobin on the surface of the raw meat;

sealing the first layer to the package;

sealing the second layer to at least one of the group consisting of the package and the first layer; and

opening the package before retail display such that the gas mixture exits the package and the carbon monoxide associated with the raw meat is removed such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package.

139. The method of claim 138, wherein a pocket is formed between the first layer and the second layer.

140. The method of claim 138, wherein the second layer is at least sealed to the first layer, and the opening of the package includes removing the second layer from the first layer before retail display such that the gas mixture exits the package through the first layer.

141. The method of claim 138, wherein the second layer is at least sealed to the package and the opening of the package includes removing the second layer from the package before retail display such that the gas mixture exits the package through the first layer.

142. The method of claim 138, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects generally laterally outwardly therefrom.

143. The method of claim 138 further including supplying an oxygen scavenger.

144. The method of claim 138, wherein the oxygen level in the package is less than 1,000 ppm.

145. The method of claim 144, wherein the oxygen level in the package is less than about 500 ppm.

146. The method of claim 138, wherein removing oxygen from the package includes evacuating the package.

147. The method of claim 138, wherein removing oxygen from the package includes flushing the package with the gas mixture.

148. The method of claim 138, wherein the gas mixture further comprises nitrogen, carbon dioxide or the combination thereof.

149. The method of claim 138, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

150. The method of claim 138, wherein the gas mixture consists of from about 0.1 vol.% to about 0.6 vol.% carbon monoxide with the remainder carbon dioxide.

151. The method of claim 138 further including placing the retail cut of raw meat on a foam tray.

152. The method of claim 138, wherein the portion being substantially permeable to oxygen comprises a polyolefin or a polyvinyl chloride overwrap.

153. The method of claim 138, wherein the gas mixture is supplied to the package such that the oxymyoglobin substantially converts directly to carboxymyoglobin.

154. The method of claim 138, wherein the oxymyoglobin substantially converts to deoxymyoglobin before the gas mixture is supplied to the package so as to convert deoxymyoglobin directly to carboxymyoglobin.

155. The method of claim 138, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.

156. The method of claim 138, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

157. A modified atmosphere package, comprising:

a package being configured and sized to fully enclose a retail cut of raw meat, the meat having meat pigment, the package having a mixture of gases comprising from about 0.1 to about 0.8 vol.% carbon monoxide and at least one other gas to form a low oxygen environment so as to form carboxymyoglobin on a surface of the raw meat;

a first layer having at least a portion being substantially permeable to oxygen and sealed to the package; and

a second layer being substantially impermeable to oxygen and sealed to at least one of the group consisting of the package and the first layer,

wherein the package is adapted to be opened such that the raw meat is allowed to be exposed to the ambient atmosphere and wherein the carbon monoxide associated

with the raw meat is adapted to be removable such that the color of the meat pigment is not fixed and turns brown in a natural time period upon opening of the package.

158. The package of claim 157, wherein a pocket is formed between the first layer and the second layer.

159. The package of claim 157, wherein the second layer is at least sealed to the first layer, the second layer being adapted to be removed from the first layer such that the raw meat is allowed to be exposed to the ambient atmosphere.

160. The package of claim 157, wherein the second layer is at least sealed to the package and the second layer is adapted to be removed from the package such that the raw meat is allowed to be exposed to the ambient atmosphere.

161. The package of claim 157, wherein the package includes a bottom wall, a continuous side wall, and a continuous rim, the continuous side wall encompasses the bottom wall and extends upwardly and outwardly from the bottom wall, the continuous rim encompasses an upper edge of the continuous side wall and projects laterally outwardly therefrom.

162. The package of claim 157 further including supplying an oxygen scavenger.

163. The package of claim 157, wherein the oxygen level in the package is less than 1,000 ppm.

164. The package of claim 157, wherein the oxygen level in the package is less than about 500 ppm.

165. The package of claim 157, wherein the gas mixture consists essentially of from about 0.1 to about 0.8 vol.% carbon monoxide, from about 40 to about 80 vol.% nitrogen and from about 20 to about 60 vol.% carbon dioxide.

166. The package of claim 157, wherein the package further includes a foam tray sized to hold the meat.

167. The package of claim 157, wherein the gas mixture comprises from about 0.3 to about 0.5 vol.% carbon monoxide.

168. The package of claim 157, wherein the gas mixture comprises from about 0.1 to about 0.5 vol.% carbon monoxide.

11. EVIDENCE APPENDIX

Exhibit 1 – Declaration of Mr. Gary DelDuca

Exhibit 2 – Second Declaration of Mr. Gary DelDuca

Exhibit 3 – Third Declaration of Mr. Gary DelDuca

Exhibit 4 – Fourth Declaration of Mr. Gary DelDuca

Exhibit 5 – Declaration of Dr. Melvin C. Hunt

- Exhibit A – Curriculum Vitae of Dr. Melvin C. Hunt
- Exhibit B – Pactiv GRAS Notice

Exhibit 6 – "The Storage Life Of Beef And Pork Packaged In An Atmosphere With Low Carbon Monoxide And High Carbon Dioxide" by Sorheim et al.

Exhibit 7 – 1962 letters between FDA and Whirlpool Corporation

Exhibit 8 – Color Atlas & Textbook of Hematology, Wm Platt, 2nd edition 1979

Exhibit 9 – 21 U.S.C. § 121.1060 dated August 2, 1961

Exhibit 10 – 21 U.S.C. § 121.1060 dated December 14, 1962

Exhibit 11 – 21 C.F.R. § 173.350

Exhibit 12 – FDA No Questions Letter from 2002/2003 to Pactiv from Eric Greenberg

Exhibit 13 – FDA letter to Cryovac

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

DECLARATION OF GARY R. DELDUCA UNDER 37 C.F.R. § 1.132

Mail Stop Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below.

October 7, 2003 — Adrienne White
Date

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering From Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco Packaging Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified

packaging for meat and processes using the same. In 1999, Tenneco Packaging Inc. was renamed Pactiv Corporation.

4. The present invention is directed to modified atmosphere packaging and methods of making the packaging that includes carbon monoxide (CO). The invention has several advantages: (a) the "seasoning" period of the raw meat may be reduced or eliminated; (b) the ability to obtain consistent blooming with cuts off pigment-sensitive meats (*e.g.*, round bone) is improved; and (c) the ability to avoid "fixing" the color of the meat pigment to red. *See, e.g.*, page 11, line 29 - page 12, line 15; page 13, lines 11-17 of the application.

5. The "seasoning" period is the time period needed to diffuse the oxygen so that the meat has the ability to fully bloom. Page 3, lines 17-19 of the application. Trays, such as polystyrene foam trays, have a substantial amount of oxygen contained in its cellular structure that results in a time period of as long as about 5 to about 6 days to diffuse the oxygen contained in its cellular structure. Page 3, lines 21-23 of the application. If a foam tray is not used, the "seasoning" period can be reduced to one or two days. Page 3, lines 24-25 of the application. The reduction or elimination of the seasoning period "allows the meat to be displayed for retail sale much sooner than in existing low oxygen packaging systems." Page 11, line 32 - page 12, line 2 of the application. Seasoning periods are not desired by the retailers or packers because of the "need to store and maintain the meat-filled packages for an extended duration before being opened for retail sale." Page 3, lines 27-28 of the application.

6. Importantly, the present invention does not "fix" the color of the meat pigment to red with its use of CO, but rather the meat pigment tends to turn brown in a natural time period. *See* page 12, lines 10-12 of the application.

7. It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but has an unacceptable amount of bacteria. The present invention "surprisingly allows the meat pigment to convert to metmyoglobin in a similar fashion as fresh, raw meat in a retail environment." Page 12, lines 7-10 of the application. Specifically, the color of the meat after exposure to the ambient atmosphere degrades in a fashion not beyond the point of microbial soundness as if the CO had never been added to the modified packaging system.

8. The meat used in the modified atmosphere packaging of the present invention substantially maintains its color during the shipping process because the package has a modified atmosphere that includes from about 0.1% to about 0.8% CO. In one method, after removal of the substantially impermeable layer, the CO is lost to the atmosphere. *See* page 12, lines 2-6 of the application. The CO may be lost to the atmosphere through the first layer that includes a portion that is substantially permeable to oxygen. *Id.* and page 13, lines 5-10 of the application. This allows the conversion of the carboxymyoglobin to oxymyoglobin by using the oxygen from the air. Page 12, lines 4-7 of the application. The "gas mixture used in the modified atmosphere packages of the present invention, after removal, allows the carboxymyogolobin to convert to oxymyoglobin and then to metymyoglobin (brown) in a natural time period." Thus, the present invention does not "fix" the color. Page 12, lines 3-5 of the application.

9. Carbon monoxide (CO) has not been allowed to be used with fresh meat in the United States for about 40 years. The Food and Drug Administration ("FDA") regulation that currently prevents using CO with meat packaging systems in the United States is 21 C.F.R. § 173.350.

10. The concern of the FDA is believed to be that CO fixes the fresh meat color to a degree that allows the retailer to sell meat that looks good (a bright red color), but is unsafe and potentially dangerous to consume because it has unacceptable levels of bacteria. This act of fixing the meat color to a bright red color is referred to as "economic adulteration."

11. After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of "fixing" the meat color.

12. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 10/1/03

Gary R. DelDuca

Gary R. DelDuca

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

SECOND DECLARATION OF GARY R. DELDUCA UNDER 37 C.F.R. § 1.132

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

October 14, 2004
Date

Adrienne White

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering from Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco, Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco

Packaging, Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified atmosphere packaging for meat and processes using the same. In 1999, Tenneco Packaging, Inc. was renamed Pactiv Corporation ("Pactiv").

3. I am a co-inventor of the present application that is directed to methods of manufacturing a modified atmosphere packaging and modified atmosphere packaging. I am familiar with the claims in the present application.

4. After about 40 years of not allowing CO to be used with fresh meats in the United States, the Applicants came up with novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoided the concerns of "fixing" the meat color, which can mask the spoilage or extend the life beyond the point of microbial soundness. The problem of fixing color using CO is known to those skilled in the art. One example of a reference that recognizes this problem is an article entitled "The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon monoxide" to Sorheim, Nissen and Nesbakken. This article was discussed in the Office Action dated May 7, 2003 in the present application.

5. One example of a meat packaging system using CO in a modified atmosphere that avoided the fixing of the meat color was Pactiv's improved ActiveTech® meat packaging system. Pactiv's improved ActiveTech® meat packaging system includes meats being placed in polystyrene trays and covered with oxygen-permeable, polyvinyl chloride ("PVC") overwraps. The wrapped trays of meat are then placed in an outer barrier bag. Ambient air is removed and replaced with a blend of 0.4 vol.% carbon monoxide (CO), 30 vol.% carbon dioxide, and the balance being nitrogen.

6. The FDA stated that it had no questions regarding Pactiv's conclusion about Pactiv's improved ActiveTech® meat packaging system using 0.4% CO being GRAS because of the evidence presented by Pactiv in its GRAS notice. *See* Exhibit A. This FDA review allows Pactiv to use CO with fresh meat in its application. It is believed to be the first system to overcome the prohibition of CO with fresh meat in the U.S. in the last 40 years. Thus, an important advancement in the art of meat packaging systems was accomplished by the use of Pactiv's improved ActiveTech® meat packaging system.

7. Besides Pactiv's improved ActiveTech® meat packaging system, the Applicants invented other novel approaches of using CO in modified atmosphere packaging (MAP) systems that avoid the concerns of "fixing" the meat color. Some of these other novel approaches include low oxygen environment, meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture including 0.4 vol.% CO.

8. An example of a low oxygen environment, meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. A peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. The first layer is located closest to the meat, while the second layer is located farthest from the meat. The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the substantially permeable first layer.

9. It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap).

10. The process of manufacturing the above-described peelable system is an example of a process that would be covered by independent claims 38, 119 and 138 of the present application. The above-described peelable system is an example of modified atmosphere packaging that would be covered by independent claims 76 and 157 of the present application.

11. One company that makes such a peelable system using 0.4 vol.% CO is Cryovac, which is marketed under the name Darfresh®. Cryovac's Darfresh® meat packaging system includes two layers – a first layer being a permeable layer and a second layer being an impermeable layer. The second layer is adapted to be removed at the point of sale by a tab so as to allow CO to escape from the package. The atmosphere within the package equilibrates with the standard atmosphere outside the package.

12. In a GRAS (Generally Recognized as Safe) notice to the FDA, Cryovac represented that this change in the atmosphere within the Cryovac package by removing the second layer "allow[s] the meat pigment color to change over time as though it has not been exposed to CO. As a result, the "FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 00083 [which is directed to the above-discussed Pactiv's improved ActiveTech® meat packaging system] ." Exhibit B. Thus, both Cryovac and the FDA believe that such a peelable system using 0.4 vol.% CO does not fix the color of the meat pigment to red.

13. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: October 14, 2004

Gary R. DelDuca

Gary R. DelDuca

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

THIRD DECLARATION OF GARY R. DELDUCA UNDER 37 C.F.R. § 1.132

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

12/6/2005 Date — Adrienne White

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering From Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco Packaging Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified atmosphere

packaging for meat and processes using the same. In 1999, Tenneco Packaging Inc. was renamed Pactiv Corporation ("Pactiv").

3. One important aspect of the present invention is that the present invention does not "fix" the color of the meat pigment to red with its use of carbon monoxide (CO), but rather the meat pigment tends to turn brown in a natural time period after removal of the second package that is substantially impermeable to oxygen. It is important to prevent the meat color from being "fixed" because it is unsafe (and potentially dangerous) to consume a piece of meat that has a bright red color that consumers associate with freshness, but is beyond the point of microbial soundness. The term "fix" in this context does not mean that the color of meat pigment never changes to a brown color, but rather that the meat pigment does not turn brown in a natural time period after the meat pigment is exposed to the atmosphere.

4. It is known to those skilled in the art that when hemoglobin in the red blood cells is exposed to CO, it has a much greater affinity than oxygen does with hemoglobin. In fact, when hemoglobin in the red blood cells is exposed to CO, the CO has an affinity 200 times greater than oxygen with hemoglobin. Therefore, one skilled in the art would expect that CO "fixes" the color of the meat pigment past its natural time period upon exposure to the atmosphere. In other words, because of the hemoglobin's high affinity towards CO, the pigment of the meat, prior to Applicants' invention, would not have been expected to degrade in a natural time period.

5. I have read the Office Action dated August 12, 2005 and the applied references of U.S. Patent No. 3,459,117 to Koch and U.S. Patent No. 6,042,859 to Shaklai.

6. U.S. Patent No. 3,459,117 to Koch discloses (a) covering primal cuts made at a slaughterhouse with a film that contains a small quantity of CO, (b) removing the CO-containing film at the retail outlet, and (c) cutting the primal cuts into individual steaks, roasts, etc.

7. "Primal" cuts of meat at the time of the Koch disclosure (late 1960's), however, generally refers to sections of meat from anywhere between about 50 and 150 or more lbs. The term "subprimal" cuts of meat is used today and generally refers to cuts of meat from about 15 to about 20 lbs. Thus, it is clear that the term primal cuts of meat in Koch refers to a large quantity of meat.

8. It would not be reasonable to one of ordinary skill in the art that a 50-150 lb piece of meat disclosed in Koch that had been exposed to a small quantity of CO would turn the non-

surface meat pigments, which were not exposed to CO, to carboxymyoglobin. This is supported by the disclosure of U.S. Patent No. 6,042,859 to Shaklai. The disclosure of Shaklai with 100% CO (as compared to the small quantity of CO in Koch) took over 7 days to saturate a small piece of meat with CO. Specifically, in Example 3 of Shaklai, 0.5 to 1.5Kg (about 1.4 lbs to about 4.2 lbs) took 7 days upon exposure to 100% CO to turn the meat pigment to carboxymyoglobin. Therefore, when the primal cuts of meat of Koch were cut at the retail outlet into individual steaks and roasts, the meat pigments of such individual steaks and roasts had not been exposed to the CO from the CO-containing film.

9. It would be expected that the individually cut steaks and roasts sections of Koch that were not exposed to CO would degrade in a manner similar to other similar cuts of steaks and roasts that had also not been exposed to CO. Thus, Koch teaches that meat pigment in the form of individual steaks and roasts <u>not</u> exposed to CO in the CO-containing film would degrade in a similar manner of steaks and roasts not treated with CO. Thus, Koch does not teach or suggest that the use of CO turns meat pigments brown in a natural time period after removal of the CO-containing film.

10. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

<u>Date: December 6, 2005</u>

Gary R. DelDuca

Gary R. DelDuca

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Jyoti Chawla
Docket No.	:	47097-01106USC1

FOURTH DECLARATION OF GARY R. DELDUCA UNDER 37 C.F.R. § 1.132

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

5/24/2006
Date

Adrienne White

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

Dear Commissioner:

I, Gary R. DelDuca, declare that:

1. I hold a degree of B.S. in Mechanical Engineering From Rochester Institute of Technology in Rochester, New York that was obtained in 1980.

2. From 1980-1995, I worked as a developmental and senior engineer for Mobil Chemical Company, Plastics Division. As a developmental engineer, I worked in process and product development in the area of foam products. As a senior engineer, some of my responsibilities included designing specialized machinery that included machinery directed to stacking trays for meat processes. Mobil Chemical Company, Plastics Division was purchased by Tenneco Inc. in 1995. From 1995 to the present, I have been a Technical Manager for Tenneco Packaging Inc. in the area of modified atmosphere packaging (MAP) for meats. My responsibilities have included designing, developing, and implementing such modified

atmosphere packaging for meat and processes using the same. In 1999, Tenneco Packaging Inc. was renamed Pactiv Corporation.

3. I am aware of the Office Action dated February 24, 2006 and have read the portion of the Office Action discussing the phrase "turns brown in a natural time period." This phrase is used in independent claims 38, 76, 119 and 138 and disclosed in the patent application at, for example, page 11, line 29 – page 12, line 15.

4. The phrase "turns brown in a natural time period" is a phrase that is used and understood by those skilled in the art. This phrase has been used in correspondence related to meat-packaging systems between retailers and myself. Specifically, this phrase has been used by those skilled in the art in the context of the color of the meat pigment. It is important to retailers and food packers that the color of the meat pigment not be fixed and turns brown in a natural time period.

5. One example of this phrase being used in the published literature is shown in Exhibit A (Principles and Applications of Modified Atmosphere Packaging of Food). On page 283, the literature discusses the effect of the meat turning brown in connection with conventionally overwrapped trays and also discusses that the color stability is limited on the shelf-life depending on type of meat (muscle).

6. The portion "turns brown" of the phrase "turns brown in a natural time period" means that the piece of meat has some brown, but does not mean that the piece of meat has to be 100% brown. Retailers and food packers use the phrase "turns brown" in the context of whether most customers would consider the color of the meat pigment undesirable such that the customers would not purchase the meat. The phrase "turns brown" is frequently used by retailers and food packers and, thus, is not indefinite.

7. The term "natural time period" of the phrase "turns brown in a natural time period" cannot be uniquely defined because the color of the meat pigment varies between the type of meat and the conditions for displaying such meat. *See* page 20, lines 17-26 of the present application ("The display times varied based on product type, initial microbial loads and storage conditions."). The natural time period for the meat pigment turning brown is not the same between ground beef, strip loins (strip steaks), inside portion of inside round steaks, outer portion of inside rounds steaks, and tenderloins. For example, the natural time period in which the meat

pigment turns brown is about 4 days for strip steaks, while the natural time period in which the meat pigment turns brown for tenderloin is about 1 day.

8. I am not aware of any standard test for determining the color of the meat pigment. The most common type of testing for determining the color of meat pigment is a visual inspection to determine whether the color of the meat pigment is acceptable for sale. As discussed in the patent application, the color of the meat pigment can be visually determined. Page 20, line 27 – page 21, line 6 of the present application. In the examples of the present application, the color of the meat pigment was visually determined using a five-point scale where 1 = very bright red, 2 = bright red, 3 = slightly dark red or tan, 4 = moderately dark red or tan, and 5 = extremely dark red or brown. Page 20, lines 28-30 of the present application. If the score was 3.5 or less, than it was visually determined that the meat pigment was an acceptable color. Page 20, lines 30-31 of the present application.

9. Alternatively, there are other tests that are used to determine the redness of the meat pigment. One example of a test for redness was disclosed in the present application at page 21, lines 7-16. In this test, examples were instrumentally analyzed for redness (a*) using a colorimeter or photometer. *See* page 21, lines 8-11 of the present application. Normally, a* values (higher values indicate more redness) are highly correlated to visual appraisal. Page 21, lines 12-13 of the present application. This type of test is not more accurate than a visual inspection by those skilled in the art because the color of the meat pigment does not degrade in a uniform fashion. Thus, some portions of the meat pigment may be brown and other portions of the meat pigment may be red, which may make the a* test less accurate than visual inspection.

10. In summary, the phrase "turns brown in a natural time period" as used in the context of independent claims 38, 76, 119 and 138 is understood by those skilled in the art and is not an indefinite phrase in this context.

11. In the Office Action dated February 24, 2006, it is stated that Woodruff "provide[s] evidence that CO is removably associated with a meat surface." Page 9. The Office Action continues by stating that "Woodruff recommends CO treatment at 0.5% volume and teaches storage of the meat at 29-40°F (column 2, lines 50-60) and for different time periods (Examples 1-VII) for meat treatment and storage and his results teach the reversibility of carboxyhemoglobin/carboxymyogolobin." Page 10. The Office Action then concludes that

Woodruff does not teach "the presence of stable bright color of meat that lasted beyond the time of spoilage (i.e., permanent binding of CO with meat pigment.)" *See* page 11.

12. Woodruff does not teach or suggest that the color of the meat pigment turns brown in a natural time period. For example, Woodruff in Example 1 discloses a 0.5 lb. beefsteak that was exposed to 0.5% CO, which was nearly all absorbed two days later. *See* col. 4, lines 34-48. After being exposed in a modified atmosphere that included 16% oxygen, "the beefsteak retained its good red color, and the carboxymyoglobin color had penetrated no more deeply than it had at the end of the two days." *See* Col. 4, lines 49-54. This passage implies that the carboxymyoglobin color was still retained within the beefsteak after 6 days despite being exposed to an atmosphere with a generally similar amount of oxygen as in air (compare about 21% oxygen to 16% oxygen). It would be expected to one skilled in the art that the beefsteak would turn brown in about 2-3 days, depending on the cut of meat. Thus, this example clearly shows that the beefsteak of Woodruff in Example 1 did not turn brown in a natural time period, but rather "fixed" the color of the meat pigment. Similarly, in Example 1 of Woodruff, a 0.5 lb. beefsteak exposed to 2.5% CO under similar conditions also retained its good color after 6 days. *See* col. 4, line 55- col. 5, line 6.

13. None of the other examples of Woodruff supports a modified atmosphere package wherein the CO associated with the raw meat is adapted to be removed such that the color of the meat pigment is not fixed and turns brown in a natural time period. Rather, the other examples of Woodruff generally disclose the condition of the meat pigment while being stored in a modified atmosphere containing CO.

14. In summary, Woodruff does not disclose, teach or suggest that the use of CO on meat pigment turns brown in a natural time period, but rather Woodruff teaches and suggests "fixing" the color of the meat pigment in Example 1.

15. In the Office Action dated February 24, 2006, it is stated that Koch "do[es] not teach the right size of the meat, Koch et al., teach the use of their package for primal as well as the final cuts (column 3, lines 4-17)." Page 11. Koch discloses that "[o]f course, if desired, the final cuts rather than just the primal cuts may be individually wrapped in the cover such as shown in FIGS. 1 and 2, this cover preferably being replaced with a conventional cover by the retailer." Col. 3, lines 13-16. This passage, however, does not disclose, teach or suggest that the color of the meat pigment is not fixed and will turn brown in a natural time period. Furthermore, this passage has nothing to do with the statement in the Office Action directed to Koch on the meat color ("Koch et al. teach a meat surface that has been exposed to CO for 7 days during storage under a modified atmosphere will remain red in color for 3 days after being removed from the modified atmosphere package[] and packaged in conventional wrapper at the retail outlet"). *See* page 6 of the Office Action. Rather, Koch discloses "[w]hen the primal cuts arrive at the retail outlet, the covers are removed and the meat is cut into individual steaks, roasts, etc which may be separately wrapped in conventional wrapping materials. It has been found that meat will release a saleable red color for as long as 10 days when covered with the cover herein described for the first seven days and with a conventional cover for the remaining days."). Col. 3, lines 5-13 of Koch (underlining added).

16 I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date 5/24/2006

Gary R. DelDuca

Gary R. DelDuca

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/965,426
Applicant	:	Gary R. DelDuca *et al.*
Filed	:	September 27, 2001
Title	:	Modified Atmospheric Packages and Methods for Making the Same
TC/A.U.	:	1761
Examiner	:	Robert A. Madsen
Docket No.	:	47097-01106USC1

DECLARATION OF DR. MELVIN C. HUNT UNDER 37 C.F.R. § 1.132

Mail Stop Amendment-Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment-Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313 on the date indicated below:

October 14, 2004
Date

Adrienne White

Dear Commissioner:

I, Dr. Melvin C. Hunt, declare that:

1. I hold a degree of B.S. in Animal Husbandry from Kansas State University in Manhattan, Kansas that was obtained in 1965. I hold a degree of M.S. in Animal Science from Kansas State University that was obtained in 1970. I hold a degree of Ph.D. in Food Science from the University of Missouri in Columbia, Missouri that was obtained in 1973.

2. From 1973-1975, I worked as a research chemist for Tennessee Eastman Company in Kingsport, Tennessee in the Health and Nutrition Division. Since 1975 to the present, I have held various professor positions at Kansas State University. Since 1991, I have been the Chair of

the Undergraduate Food Science Program at Kansas State University. I have taught several courses over the years at Kansas State University including: Meat Science, Processed Meat Operations, Advance Meat Science, Food Science Seminar, Topics in Meat Science and Muscle Biology, Meat Processing, and Livestock and Meat Evaluation. I have also performed numerous research projects in Meat Science and Muscle Biology including major emphasis on pigment chemistry, meat color, meat packaging, and factors effecting microbial soundness (shelf life) of meat. Thus, I have extensive experience in the processing of meat using modified atmosphere packaging.

3. My curriculum vita (attached as Exhibit A) details my professional affiliations related to animal science and meat science. I have served as President of the American Meat Science Association in 1995-1996, Chair of the Meat Science-Muscle Biology Section of National American Society of Animal Science ("ASAS"), Chair of the Midwestern ASAS Meat Science Section, and Chair of the Muscle Foods Division of the Institute of Food Technologists. I have been on the Editorial Board of the publication entitled "Journal of Muscle Foods." I also perform manuscript review for several peer-reviewed scientific publications including "Meat Science", "Journal of Muscle Foods", "Journal of Animal Science", and "Journal of Food Science."

4. I assisted in preparing some of the information included in Pactiv's GRAS notice (Exhibit B) that was filed with the Food and Drug Administration (FDA) on August 29, 2001. The specific modified atmosphere packaging (MAP) system that was presented in the GRAS notice was a meat packaging system containing 0.4 vol.% CO and was referred to in the notice as Pactiv's ActiveTech® meat packaging system. The ActiveTech® meat packaging system placed meat in polystyrene trays, which were covered with oxygen-permeable, polyvinyl chloride (PVC)

overwraps. The wrapped trays of meat were then placed in an outer barrier bag. Air was removed and replaced with a blend of 0.4 vol.% CO, 30 vol.% carbon dioxide, and the balance being nitrogen.

5. I performed a series of tests on the effects of the ActiveTech® meat packaging system with CO on fresh meat color, color stability, and shelf life. The conclusions reached for the ActiveTech® meat packaging system with CO were: (a) the color of Pactiv's ActiveTech® meat packaging system using CO resulted in products that were equally red to products packaged with traditional oxygen permeable overwrap; (b) color deterioration of meat during simulated retail display in Pactiv's ActiveTech® meat packaging system using CO compared well to products packaged with traditional oxygen permeable overwrap; (c) bacterial growth was neither encouraged nor suppressed by adding CO to Pactiv's ActiveTech® meat packaging system; and (d) CO in the ActiveTech® meat packaging system neither masked spoilage, nor extended color life beyond the point of microbial soundness. I further concluded that Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO might be eligible for GRAS status.

6. The results of the testing were surprising to me because it was understood by those skilled in the art that CO fixes (creates a stable form of myoglobin that could mask spoilage) the color of the meat pigment to red. This is believed to be the reason on why CO had not been allowed to be used with fresh meat in the United States for many years. Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO, however, did not fix the color of the meat pigment to red. Rather, the meat pigment turned brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap). This was a novel result and was not at all obvious due to the current and long standing thought that meat

exposed to CO would develop a color that would mask spoilage. In other words, the pigment of the meat when exposed to CO would produce an extremely stable form of the pigment, but this did not happen in the Pactiv Active Tech® system.

7. I also believe that the surprising results obtained in the testing of the ActiveTech® meat packaging system using 0.4 vol.% CO would be equally applicable to other low oxygen environment meat packaging systems having (a) a first layer being a substantially permeable layer, (b) a second layer being a substantially impermeable layer, and (c) a gas mixture containing 0.4 vol.% CO.

8. An example of a low oxygen environment meat packaging system that uses (a) a first layer being a substantially permeable layer and (b) a second layer being a substantially impermeable layer is a "peelable" system. The peelable system typically places a piece of meat on a tray in which the tray is sealed by a first layer that is substantially permeable and a second layer that is substantially impermeable. The first layer is located closest to the meat, while the second layer is located farthest from the meat. The second layer is then peeled apart from the first layer such that the gas mixture contained within the package exchanges with the atmosphere through the permeable first layer.

9. It is believed that using such peelable systems with 0.4 vol.% CO would not fix the color of the meat pigment to red. Rather, the meat pigment would turn brown (discolored) in a pattern typical of retail meat in display but packaged in a standard supermarket format (foam tray and PVC overwrap).

10. Prior to Pactiv's Active Tech® system using 0.4 vol.% CO, there was a need in the industry to provide a solution that: (a) reduced the seasoning period (the critical time meat is

exposed to low partial pressures of oxygen, which can seriously damage the pigment chemistry); (b) formed consistently a normal bloomed color with meats whose pigment is sensitive to metmyoglobin formation; and (c) avoided the fixing of too stable of a meat color, which can be unsafe and potentially dangerous, if the color stability was greater than the shelf life (microbial soundness) of the product. Such a solution was especially desirable for a centralized packaging facility where the meat would be shipped to distant locations.

11. Systems such as (a) Pactiv's ActiveTech® meat packaging system using 0.4 vol.% CO or (b) those systems having (i) a first layer being a substantially permeable layer, (ii) a second layer being a substantially impermeable layer, and (iii) a gas mixture containing 0.4 vol.% CO such as the above-described peelable system are new and novel approaches that address these technological needs.

12. I hereby declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: Oct 6, 2004

Melvin C Hunt
Dr. Melvin C. Hunt

“A”

MELVIN C. HUNT

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PERSONAL DATA:
Born: February 10, 1942
Married: Rae Jean Opie, August 20, 1965; Daughters: Paige and Holly

EDUCATION:
B.S. 1965 Animal Husbandry, Kansas State University, Manhattan, KS
M.S. 1970 Animal Science, Kansas State University, Manhattan, KS
Ph.D. 1973 Food Science, University of Missouri, Columbia, MO

PROFESSIONAL EXPERIENCE:
1991- Chair, Undergraduate Food Science Program
1984- Professor, Kansas State University: 50% Teaching - 50% Research
1978-84 Associate Professor, Kansas State University
1975-78 Assistant Professor, Kansas State University
1973-75 Research Chemist, Tennessee Eastman Company
1968-73 Grad Research Assistant, Kansas State and University of Missouri
1966-68 Taught high school chemistry and biology, Kinsley, KS

PROFESSIONAL AFFILIATIONS:

American Meat Science Association:
- President, 1995-96; Past-President, 1996-97
- Director and Executive Board, 1989-91
- Chair 1991 Reciprocal Meat Conference
- Parliamentarian
- Chair or member of numerous committees including:
  Meat Color Guidelines, AMSA Teaching Award, Undergraduate Travel Award, Grad Student Poster Competition, Teaching Display, Resolutions, Meat Tenderness, Biochemistry-Biophysics, Packaging, Meat Color, Growth and Development, Reciprocation, Long Range Planning, Sustaining Membership, Endowment, and Research Priorities.

American Society of Animal Science:
- Chair and Chair-elect, Meat Science-Muscle Biology Section of National ASAS Meeting
- Chair, Midwestern ASAS Meat Science Section
- Editorial Board Journal Animal Science
- Teaching Award Committee, Midwestern ASAS Section

Institute of Food Technologists:
- Chair and Chair-elect of Muscle Foods Division, 1992-94
- Director of Muscle Foods Division
- Chair of Muscle Foods Nominating Committee
- Committee for two National Muscle Foods Symposia
- Journal of Food Science, Manuscript Review

CAST: Contributing member

Journal of Muscle Foods: Editorial Board

HONORARY AFFILIATIONS:
Phi Kappa Phi, Sigma Xi, Phi Tau Sigma, Gamma Sigma Delta, Alpha Zeta

HONORS:
- College of Agriculture Outstanding Faculty Award 1979
- College of Agriculture Outstanding Faculty Award 1982
- College of Agriculture Outstanding Faculty Award 1988
- College of Agriculture Outstanding Faculty Award 1998
- College of Agriculture Outstanding Academic Advisor 1983
- University Selection for Parents' Day Lecture 1979
- Outstanding Lecturer Award, ITAL, Campinas, Brazil 1981
- Honorary State Farmer Degree 1985
- Distinguished Teaching Award, Gamma Sigma Delta 1989
- Selected Instructor, National Food Science Satellite Program 1990
- Certificate of Meritorious Service, Kansas Ag Teachers Association 1992
- CASE Professor of the year, Kansas winner of national competition 1992
- Outstanding Advising Award, Gamma Sigma Delta 1994
- Distinguished Teaching Award, American Meat Science Association 1994
- Outstanding Food Scientist, Phi Tau Sigma 1996
- Outstanding KSU Instructor & Advisor Award, Mortar Board 1997
- Signal Service Award, American Meat Science Association 1997
- USDA Food & Agriculture Science Excellence in Teaching Award, 2000

DEPARTMENT, COLLEGE OF AG, AND UNIVERSITY ACTIVITIES:
- Faculty Advisor: Block and Bridle, 6 years
- Faculty Advisor: Food Science Club, 3 years
- Faculty Advisor: Animal Science Grad Student Association, 16 years
- Faculty Advisor: Ag Student Council, elected for 2 terms (4 years)
- Chair, Weber Hall Building/Renovation Project
- Chair, KSU Meat Science Faculty
- Coordinator of KSU Meat Research Labs
- ASI Graduate Student Selection Committee
- ASI Undergraduate Career Development Committee
- ASI Library Committee
- ASI Scholarship, Loans and Honors Committee
- Department Representative for Gamma Sigma Delta, 10 years
- Student Team Coordinator, ASI Quadrathalon Teams
- Agriculture Student of the Month Selection Committee
- Agriculture Faculty of the Semester Selection Committee
- College of Agriculture Course and Curriculum Committee, chair and member
- College of Agriculture Academic Standards Committee, chair and member
- College of Agriculture Commencement Committee
- University Faculty Senator, College of Agriculture, two terms (6 years)
- University Academic Affairs Committee
- University Coordinating Committee for United Way
- KAES NCR-1?1 Chair and Secretary: Food & Feed Safety in Animal Production
- Food Science Undergraduate and Graduate Steering Committees
- Chair, Non-Traditional Studies Advisory Committee
- Elected by peers to ASI Teaching Advisory Committee
- Chair, KSU Undergraduate Food Science Program: Coordinate all course & curriculum and policy matters, scholarship, internships, recruitment, and record keeping

INDUSTRY-EXTENSION ACTIVITIES:
- Numerous presentations at: MidWest Meat Processors Seminars, Kansas-Nebraska Curing and Sausage Short Courses, KSU Cattlemen's Day, KSU Swine Day
- Technical Assistance for: Tennessee Eastman Company, Ross Industries, Giant Food

Stores, Excel Corporation, IBP, Doskocil Companies, Tenneco Packaging, Farmland, National Beef, Cryovac, Buckhead Beef, Dupont, Kalsec, Wendy's, Greater Omaha Beef, Hormel
- State FFA Livestock Awards Selection Committee
- State FFA Star Farmer Selection Committee
- State FFA Public Speaking Contest Judge
- Kansas Jr. Livestock Carcass Contest Judge
- Kansas Meat Processor Cured Meat Show Judge
- Missouri Meat Processor Cured Meat Show Judge

TEACHING RESPONSIBILITIES:

Current Courses - KSU Campus:

- ASI 350 Meat Science. 3hr. Lecture-lab introductory meat science
  Enrollment: Since 1979, 2031 students; currently running at maximum seating of 72
- ASI 610 Processed Meat Operations. 2hr. 50% responsibility, value-added processing
  Enrollment: 6 to 12 undergraduate and graduate students; since 1988, 35 students
- ASI 930 Advanced Meat Science. 3hr. Team-taught, highest level meats course
  Enrollment: Varies from 6 to 15 graduate students
- GENAG 500 Food Science Seminar. 1hr. Seminar for graduating seniors
  Enrollment: Varies from 6 to 15 students

Current Courses - KSU Distance Learning Program:

- ASI 340 Principles of Meat Science. 2hr. Web-based course for Continuing Education
  Enrollment: Since 1987, over 680 students
- GENAG 500 Food Science Seminar. 1hr. Seminar series for Distance Learning majors
  Enrollment: 3 to 15 undergraduate students per year, Continuing Education
- GENAG 630 Food Science Problems. 1hr. Detailed written investigation of current topics
  Enrollment: 2 to 8 students per year through Continuing Education

Previously Taught Courses:

- Topics in Meat Science and Muscle Biology
- Meats Judging Team (at University of Missouri)
- Meat Processing
- Livestock and Meat Evaluation
- Animal Agriculture and Consumers

INTERNATIONAL COURSE ACTIVITIES:

- Meat Science and Technology Short Course for Latin America, Institute for Food Technology, Campinas, Brazil, 6 weeks, one of two international lecturers
- Meat Science Facilities, University of Monterrey, Monterrey, Mexico
- Lecturer for five KSU International Meat Science Courses, International Meat and Livestock Program, Kansas State University
- Sabbatical leave, fall 1992, visiting scientist to Norwegian Food Research Institute, As
- Have attended 8 International Congresses of Meat Science and Technology

ADVISING RESPONSIBILITIES:

- Undergraduate Advisees: average of 26 for the last 10 years
  - Graduate Students Supervised:
    - 12 Masters Students
    - 6 PhD Students
  - Graduate Student Committees:
    - 43 Masters
    - 20 PhD
  - Coordinate student-company relations for employment and internships for FSI

RESEARCH INTERESTS:

- Myoglobin chemistry and meat color, Methods of color measurement, Cooked meat color and food safety, Postmortem factors affecting meat quality, Collagen chemistry, Low-fat ground beef and processed meats; Six major company packaging projects funded since 1994 dealing with shelf life, color life, cold chain management, product palatability, and microbiology

PUBLIC AND COMMUNITY ACTIVITIES:

- Manhattan Optimist Club: committees for many youth activities
- Coach, Girls (16-18) ASA fast pitch softball traveling team
- Executive Committee, Riley County Extension Council
- Asst. Superintendent, sheep division, Riley County Fair
- Judge at Manhattan High School oratorical contest
- FarmHouse Fraternity, alumni board and committee work
- Snyder Award for Alumni Service, FarmHouse Fraternity
- Activities of First Presbyterian Church

Melvin C. Hunt
Professor
Department of Animal Sciences and Industry
Kansas State University

Refereed Journal Articles

Hunt, M.C., R.A. Smith, D.H. Kropf and H.J. Tuma. 1975. Factors affecting showcase color stability of frozen lamb in transparent film. J. Food Sci. 40:637.

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Gutowski, G.H., M.C. Hunt, C.L. Kastner, D.H. Kropf and D.M. Allen. 1979. Vacuum aging, display, and level of nutrition effects on beef quality. J. Food Sci. 44:140.

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Sleper, P.S., M.C. Hunt, D.H. Kropf, C.L. Kastner and M.E. Dikeman. 1983. Electrical stimulation effects on myoglobin properties of bovine longissimus muscle. J. Food Sci. 48:479.

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Choi, Y.I., C.L. Kastner, M.E. Dikeman, M.C. Hunt and D.H. Kropf. 1984. Effects of electrical stimulation and hot boning on functional characteristics of preblended beef muscle in model systems. J. Food Sci. 49:867.

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Educational Materials

Course Syllabi:

Distance Learning - Complete course, *PRINCIPLES OF MEAT SCIENCE* in "any-time or real-time" distance learning format via audiotapes, teleconferencing, on-line discussions involving collaborative learning, problem solving and critical thinking via the Internet.

In-Class
- Laboratory Materials for *MEAT SCIENCE*, a series of 14 study guides for lab exercises
- Laboratory Materials for *PROCESSED MEAT OPERATIONS*

Other Materials and Activities:

USDA Grant: - Expanding Undergraduate Education for Food Industry Personnel via Technology. 1994-96 USDA Challenge Grant Program, $79,479

Web-based Course - Principles of Meat Science, KSU Division of Continuing Education

Color Guides
- Ground Beef Patty Cooked Color Guide
- Cured Meat Color Guide
- Cooked Pork Chop Color Guide
- Ground Pork Patty Cooked Color Guide

Science Series
- Lesson Plans for: Promoting Ag Science for Secondary Schools
  - Developing New Meat Products
  - Color Chemistry in Meat Products
  - Meat Packaging Exercises for High School Students

Slides Series:
- Unraveling the Mystery of Premature Browning in Cooked Ground Beef Patties
- Doneness of Cooked Ground Beef
- Dynamics of Conversion of Myoglobin Forms
- Role of Pigment Layers in Influencing Surface Meat Color
- Spray Chilling of Carcasses
- Don't be Broken-Hearted because of High-fat in Ground Beef
- Commercial Sausage, Ham and Bacon Production
- Food Science at KSU
- ASI Quadrathlon - why I should participate
- Updated: Muscle-Bone Anatomy; Beef-Pork-Lamb Cut Identification

Video Tapes: - Beef Carcass Electrical Stimulation and Hot Boning (Edited with M. E. Dikeman)

Store Survey: - Out-of-class assignment for Analysis of Retail Meat Section of Grocery Stores

Diet Survey: - Out-of-class assignment for computerized class project of Nutritional Value of Muscle Foods in the student's diet

Current topic: Survey - Out-of-class assignment for critically analyzing printed literature on a variety of livestock and meat industry topics

Web Sites: - Out-of-class assignment for evaluation and collection of scientific facts about muscle biology and meat science

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"B"

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Contains Confidential Business Information

August 29, 2001

Division of GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St, SW
Washington, DC 20204

Re: **NOTIFICATION OF CLAIM FOR GENERAL RECOGNITION OF SAFETY OF CARBON MONOXIDE IN A MODIFIED ATMOSPHERE SYSTEM FOR PACKAGING FRESH MEAT**

To the FDA:

This letter and its attachments contains the notification, pursuant to the Federal Food, Drug and Cosmetic Act and FDA's regulations, by Pactiv Corporation, 1900 West Field Court, Lake Forest, Illinois 60045, c/o attorney Eric F. Greenberg, 3500 Three First National Plaza, Chicago, Illinois 60602[1], for the General Recognition of Safety of carbon monoxide ("CO") at a level of 0.4% in a modified atmosphere system for packaging fresh meat.

[1] Attachment 1 contains Pactiv's authorization of undersigned counsel, as well as a Summary regarding Pactiv Corporation.

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As set forth more fully below and in the attachments to this document, Pactiv believes its intended use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30, and including FDA's proposed rule published on April 17, 1997 (62 FR 18937). FDA regulations provide that the scientific evidence available and reviewed for a GRAS determination is of the same quantity and quality as that required for a food additive approval, and that the scientific evidence of safety be generally known and accepted by qualified experts in the appropriate scientific and technical fields. 21 CFR Sec. 170.30(a).

I. Claim of Exemption

a. Name and address of the notifier.

Pactiv Corporation
1900 West Field Court
Lake Forest, Illinois 60045
c/o Eric F. Greenberg
Attorney at Law
3500 Three First National Plaza
Chicago, IL 60602

b. Common or usual name of the notified substance.

Carbon monoxide ("CO")

c. **Conditions of use (foods, levels, purposes).**

When used as described in this Notice, CO meeting appropriate purity specifications is a processing aid in packaging of fresh cuts of muscle meat and ground meat, as a component of a gas mixture utilized in a specific modified atmosphere packaging system. 21 CFR Sec. 170.3(o)(24). A technology utilizing 0.4% CO within a modified atmosphere packaging system will maintain wholesomeness, permit greater flexibility in distribution, and reduce shrinkage, all within a system that results in traditional product display to consumers. All elements of the system, excluding the CO, are already in use in the United States as part of a modified atmosphere meat packaging system called ActiveTech™. Notifier refers to the new system incorporating CO as "AT2001".

Summary

ActiveTech™ is a system that is designed to permit more extended storage of meats, but, as explained below, has no effects on retail display time or characteristics as compared with other modified atmosphere technologies currently in use. It employs materials that are either approved additives used consistently with their approvals, or GRAS substances. AT2001 adapts that system for additional storage scenarios. AT2001 serves to reduce the time needed for enzymatic reduction after modified

atmosphere packaging, and allows consistent display color of whole muscle meats. AT2001's advantages are in the resulting flexibility and consistency during storage and distribution.

The GRAS use of CO described in this Notice involves use as a component of the flush gas mixture used in replacement of ambient air in the packaging for distribution of refrigerated fresh red meat. The meats are in all instances fresh, and are intended to be cooked prior to consumption.

"Traditional" ActiveTech™

The ActiveTech™ modified atmosphere system, in commercial use in the United States since 1998, is a modified atmosphere system for packaging fresh cuts of muscle meat, or portions of ground meat. AT2001 is a refinement of ActiveTech™, and differs from it only in the addition of 0.4% CO to the modified atmosphere.

In the "traditional" ActiveTech™ system, the meats are placed in polystyrene trays and covered with oxygen-permeable, flexible polyvinyl chloride ("PVC") overwraps. The wrapped trays of meat are then placed within an outer barrier bag from which ambient air is removed and replaced with a blend of 30% carbon dioxide (CO_2) and 70% nitrogen (N_2). An activated oxygen-absorbing sachet is also added within the outer bag.

This modified atmosphere maintains the packaged meat in an oxygen-free deoxymyoglobin state, with its distinctive purplish appearance that is generally considered undesirable by consumers. The traditional ActiveTech™ system relies on the rapid reduction of the oxygen content of the outer bag. Once the oxygen is removed, a "seasoning" phase begins during which enzymatic effects take place so that the meat will be able to "re-bloom" when once again in the presence of oxygen. As the residual oxygen in the package is consumed by the activated oxygen scavenger, red meat oxymyoglobin is first subject to rapid conversion to metmyoglobin (brown) at very low partial pressures of oxygen, e.g. 0.5% oxygen. This low partial pressure region of oxygen is necessarily passed through prior to ultimately reaching 0% in the package and the conversion to deoxymyoglobin (purple). This seasoning phase can take up to 5 days.

Before display to consumers at retail, the outer bag, and thus the modified atmosphere, is removed, and the traditionally wrapped product (in polystyrene foam tray with PVC overwrap) is permitted to "re-bloom" to its familiar appearance through creation of oxymyoglobin on the meat's surface.

AT2001

In the AT2001 modified atmosphere system, as with traditional ActiveTech™, fresh cuts of muscle meat, or portions of ground meat, are placed in polystyrene trays and covered with oxygen permeable flexible PVC overwraps. The wrapped trays are placed within the outer barrier bag, the air is removed and replaced with a blend of 0.4% CO, 30% carbon dioxide (CO_2) and the balance nitrogen (N_2). As with the traditional AT system, an activated oxygen-absorbing sachet is added within the outer bag to create and maintain an oxygen-free environment for the packaged meat during storage.

As noted, meat packaged in traditional ActiveTech™ undergoes a myoglobin pigment conversion from oxymyoglobin (red) to metmyoglobin (brown) to deoxymyoglobin (purple) in the oxygen free environment. The metmyoglobin formed generally will convert to deoxymyoglobin in the oxygen free storage environment in about 5 days, a period of time referred to as the "seasoning period". However, the meat's ability to convert all of the metmyoglobin formed to deoxymyoglobin during the seasoning period and then fully rebloom to oxymyoglobin upon re-exposure to normal, oxygen-rich atmosphere at retail, is a function of a multitude of unpredictable, uncontrollable factors in the meat such as age, muscle

location, and enzyme energy level. This is a key weakness of all current low oxygen packaging systems.

Meat packaged in the AT2001 atmosphere will instead convert from oxymyoglobin to carboxymyoglobin (red) in the package due to the inclusion of 0.4% CO in the modified atmosphere. This conversion occurs during the initial 24 hours as the free oxygen in the headspace is consumed. Thus, the CO effectively protects the myoglobin from converting to metmyoglobin as the oxygen in the package is removed. This feature is especially important for the most pigment sensitive meats such as those from the round. The meat will continue to maintain its red color while in storage until the package is opened for retail display, when the outer bag (and modified atmosphere) is removed. Since carboxymyoglobin and oxymyoglobin are essentially the same colors, no seasoning period is necessary. The meat can be opened for retail display the day following packaging.

Once in retail display, the meat's myoglobin will begin the rather slow, natural conversion to metmyoglobin (brown), akin to that seen with untreated meat, allowing for a conventional retail display life of 3 to 4 days, closer to consumers' expectations of color than results from use of high

oxygen packaging systems. Attachment 2 consists of photographs depicting the ActiveTech™ and AT2001 systems.

The AT2001 formulation will assure that the meat will have the familiar color during and following storage, eliminating the seasoning period, allowing for placement in retail display beginning at 1 day, and up to 30-40 days, after packing. For cuts of meat from the round, and other color sensitive cuts, the AT2001 will help them have a more uniform red color for retail display.

In AT2001 (as in traditional ActiveTech™), the trays and films utilized are made from familiar, FDA-approved polymers that are used in accordance with their existing approvals or GRAS status. The activated oxygen-absorbing sachet inserted into the outer bag to absorb oxygen does not contact food and is not expected to become a component of the food. Therefore, it is not a food additive under the definition in 21 USC Sec. 321(s). As an added assurance of safety, each of the sachet's components has some GRAS status or food-related approvals.

Thus, the AT2001 system adds a refinement to the existing ActiveTech™ system that will allow its utilization with whole and ground meat products that meet the processors' desire to get to market as soon as the day following processing.

d. **Basis of GRAS determination: Scientific procedures**

CO safety

Pactiv believes its proposed use of CO is GRAS based on scientific procedures within the meaning of 21 U.S.C. Sec. 201(s) and FDA's implementing regulations in 21 CFR Sec. 170.30 and including FDA's proposed rule published on April 17, 1997 (62 FR 18937).

CO is a colorless, odorless gas that is poisonous to humans if inhaled at much higher levels than are involved with the use that is the subject of this Notice. It is formed when carbon is not completely burned, for example, in the combustion of fuels.

It is well known that CO creates negative health effects at elevated levels because it out-competes oxygen for attachment to the hemoglobin molecule. The resulting carboxyhemoglobin levels in the blood are associated with severe health effects. In addition, the equilibrium rate for the exchange of carboxyhemoglobin for oxyhemoglobin is very slow, and the resulting level of carboxyhemoglobin is a function of the CO level in the respired air, the time of exposure and the level of activity of the individual. Typical atmospheric CO levels are <20 mg/m^3 as an 8 hour mean (higher in

urban and high traffic areas), and typical carboxyhemoglobin levels due to natural background CO range between 1.2 and 1.5%.

CO is recognized as a significant air pollutant at higher levels. Automobile exhausts, industrial processes and boilers and incinerators all contribute to air quantities of CO. According to the U.S. EPA Office of Air and Radiation:

> Carbon monoxide enters the blood stream and reduces oxygen delivery to the body's organs and tissues. The health threat from exposure to CO is most serious for those who suffer from cardiovascular disease. Healthy individuals are also affected, but only at higher levels of exposure. Exposure to elevated CO levels is associated with visual impairment, reduced work capacity, reduced manual dexterity, poor learning ability, and difficulty in performing complex tasks. EPA's health-based national air quality standard for CO is 9 parts per million (ppm) [10 mg/m^3] measured as an annual second-maximum 8-hour average concentration.

"Summary regarding carbon monoxide" as part of discussions of 6 principal pollutants, U.S. EPA Office of Air and Radiation.

No health effects result when carboxyhemoglobin levels are under 4% to 5% in healthy adults. Carboxyhemoglobin levels of 2 to 3% may have negative effects on those with cardiovascular disease or other sensitivity. See, Environmental Health Criteria 13, Carbon Monoxide, World Health Organization, Geneva, Switzerland (1979), p. 15.

The US Occupational Safety and Health Administration's air contaminants regulation, 29 CFR Sec. 1910.1000, lists 50 ppm and approximately 55 mg/m^3 of CO as the 8-hour Time Weighted Average of exposure for the substance. 29 CFR Sec. 1910.1000.

By contrast, as explained below, the worst case estimated intake of CO attributable to AT2001 is 1.88 mg CO/meal.

The US FDA has not established an Acceptable Daily Intake for CO. Nevertheless, CO exposure, at levels much higher than those attributable to AT2001, for decades has been permitted within the existing FDA and USDA food additive regulatory provisions:

- Wood smoke ("smoke flavoring"), conventionally including CO as a component, is permitted by regulation as an ingredient in meat and poultry products pursuant to 9 CFR Secs. 318.7(c)(4)[meat], 381.147(c)(4)[poultry], 424.21(c).
- The specifications for Combustion product gas in 21 CFR Sec. 173.350 permit CO up to 4.5 percent by volume in such gases, which may be used in the processing and packaging of beverages and other foods except fresh meats, to remove and displace oxygen. Such gases are commonly used to package fruits and vegetables.

- In 2000, FDA responded favorably to GRAS Notice 000015 from Hawaii International Seafood, Inc. for the use of tasteless smoke, before freezing of tuna, as a preservative, specifically to preserve taste, aroma, texture and color. GRAS Notice (GRN) No. 000015, March 10, 2000. CO is a primary component of conventional smoke, which that Notice asserts is Generally Recognized As Safe based on decades of safe use in a variety of foods, which uses are recognized by FDA and incorporated into numerous food standards that permit smoking of cheeses. CO is also a primary component of tasteless smoke, along with nitrogen, oxygen, carbon dioxide and methane. The tasteless smoke is used to impart a "preservative effect." As noted in FDA's March 10, 2000 letter about the GRAS Notice, "In Hawaii International's view, tuna treated with tasteless smoke and tuna treated with conventional smoke contain comparable levels of carbon monoxide, carbon dioxide, hydrocarbons, and phenols." FDA's letter notes that it "has no questions at this time" regarding Hawaii International's conclusion that the use described is GRAS, though, in keeping with current regulatory practice, it had not made its own determination.

CO is listed as a reproductive toxicant by the State of California pursuant to its Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"). California law contemplates that exposures to listed reproductive toxicants will be accompanied by a warning, unless the exposure is less than 1/1000th of an established no observable effect level. Cal. Health and Safety Code, Sec. 25249.6. No such level has been established for CO. Almost without question, though, any such future level (which will have a dubious connection to safety principles in any event, due to the design of Prop. 65), will be more than 1,000 times any possible exposure that could result from AT2001. The worst-case potential exposures from AT2001 are tiny fractions of the established occupational and environmental exposure levels (see below), which themselves are certain to be well below any level at which reproductive toxicity is ultimately is deemed to result.

Effects on Fresh Meat and Consumption

Analysis of the AT2001 system makes plain the lack of any safety issue from consumption of treated meats. Additionally, similar technologies employing CO as part of a modified atmosphere gas mixture analyzed the technologies for effects on meat in terms of microbial load and organoleptic

properties including color, and for the safety of consumption of treated meats, specifically, any tendency of the consumed meat to expose consumers to levels of carboxymyoglobin. Further important evidence is obtained from examination of the actual experience since 1985 in Norway of packaging fresh red meats in 0.3 – 0.5 % CO for retail.

<u>Safety: Effects on carboxymyoglobin levels</u>

Consumption of meat treated with AT2001 is not expected to result in any measurable levels of carboxymyoglobin in the blood of those who consume treated meat.

An Estimated Daily Intake ("EDI") of CO attributable to the AT2001 use can be calculated as follows. First, we assume the following reasonable values for the exposure parameters:

(1) An AT2001 bag contains 1.5 L modified atmosphere with a CO concentration of 0.4%, that is equivalent to approximately 0.006 L of CO in the bag (= 6 mL CO).

(2) At 28 g CO per mole and approximately 22.4 L per mole, the mass of CO per unit volume may be calculated: (28 g/mol)/(22.4 L/mol) = 1.25 g/L = 1.25 mg/mL.

(3) The AT2001 bag contains 2 lbs (approximately 1.0 kg) of ground meat.

(4) Approximately 30% of the total amount of CO is absorbed into the meat (based on Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C] Carbon Monoxide in Cooked or Store Ground Beef Samples", J. Agric. Food Chem., Vol. 26, No. 1 (1978), pp. 210-214). Therefore, the amount of CO taken up by the meat is [(0.3)*(6 mL/bag)*(1.25 mg/mL)] / [1.0 kg meat/bag] = 2.25 mg CO / kg meat.

(5) If we assume that a person consumes an 8.8 oz steak (250 g = 0.25 kg meat), or ground equivalent, at a single meal[2], that 85% reduction in CO content occurs during cooking, and that 100% of the ingested CO is absorbed, then the maximum amount of CO exposure is (0.15)*(2.2.5 mg CO /kg meat)*(0.25 kg meat/meal) = 0.084 mg CO/meal.

Next, comparison may be made of the of the consumer EDI for CO to that amount inhaled during an 8-hour period at the EPA's National Ambient Air Quality Standard ("NAAQS") level. 40 CFR Sec. 50.8, National primary ambient air quality standards for carbon monoxide:

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[2] Note that this is a conservative assumption. The EDI of beef for the 90th percentile intake per user is 139.2 g/d based on the most recent USDA national survey of food intake by individuals. Pactiv chose to use a larger value for beef consumption to simulate a typical to above-average consumption incident rather than an average over all meats.

The calculated, worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the American Conference of Governmental Industrial Hygienists ("ACGIH") Threshold Limit Value ("TLV"). Documentation of the Threshold Limit Values and Biological Exposure Indices, p. 23, ACGIH, 1330 Kemper Meadow Drive, Cincinnati, Ohio.

(1) The ACGIH TLV is 25 ppm CO is equivalent to approximately 28.9 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(28.9 \text{ mg/m}^3)^*(5 \text{ m}^3/8\text{-hr}) = 145 \text{ mg CO / 8-hr.}$$

Thus, the ingestion of residual CO from the cooked meat is merely 1.3% of the exposure level at ACGIH TLV ((1.88 mg) / (145 mg) = 0.013 = 1.3%)

Finally, the calculated worst case consumer EDI for CO may be compared to that amount inhaled during an 8-hour period at the OSHA PEL:

(1) The OSHA PEL is 50 ppm CO is equivalent to approximately 58 mg CO per m^3 air.

(2) The typical person breathes 15 m^3 air per day or approximately 5 m^3 air per 8-hours.

(3) The exposure under these circumstances may be calculated as follows:

$$(58\ mg/m^3)*(5\ m^3/8\text{-}hr) = 290\ mg\ CO\ /\ 8\text{-}hr.$$

Thus, the ingestion of residual CO from the cooked meat is 0.65% of the exposure level at OSHA PEL. ((1.88 mg) / (290 mg) = 0.0065 = 0.65%).

Thus, the consumer EDI of CO from a eating meat packaged in the Active Tech 2001 bag is a small fraction of any of the currently allowed exposures by authoritative agencies. As these various limits were established to protect individual safety and health, it is plain that the worst case exposures that may result from AT2001 present no safety concerns whatsoever.

In the 1997 study, "Technological, hygienic and toxicological aspects of carbon monoxide used in modified-atmosphere packaging of meat" Trends in Food Science and Technology, September 1997 [Vol. 8], pp. 307-312, Sørheim, et al. concluded that meat packaged and displayed in an atmosphere combining 60 to 70% carbon dioxide, 30 to 40% nitrogen, and less than 0.5% CO "will result in only negligible levels of carboxyhemoglobin in the blood."

The authors note that there was sparse information in published literature on exposure to CO after consumption of meat treated with CO gas. They note that "the inhalation of air containing CO at a level of 55 mg per m^3 (the acceptable level in working environments in the USA) would provide a COHb level for a prolonged time period (hours) of at least 14 times that of the level reached temporarily on the consumption of 225 g of meat that has been packaged in CO at the saturation level for myoglobin." That estimate assumed saturation of meat myoglobin and hemoglobin was maximal and the transfer of CO from the gastrointestinal tract to the blood was 100%. Sørheim, et al. (1997), p. 310. The authors concluded, "Consequently, even for such a "worst case" scenario, the treatment of meat with CO gas appears to contribute very little to COHb levels, relative to levels that are considered safe in the working environment." Sørheim, et al. (1997), p. 310.

The authors report that "CO is lost from previously CO-treated meat during storage in the absence of CO, with a half life of ~3d." Sørheim, et al. (1997), p. 310. As these fresh meats are to be cooked before consumption, CO lost during cooking is also relevant. The authors report that "When the beef was cooked at 195° C, only 0.1 mg of CO remained

per kg of meat. The loss of CO amounted to ~85%." Sorheim, et al. (1997), p. 310.

The authors also compared CO exposure from the air and estimated exposure from CO-treated meat. Their comparative table is shown below.

Table 5. Theoretical Uptake of Carbon Monoxide (CO) in Blood

Exposure method	CO intake in 1 h	CO intake in 8 h
Lungs (15m ^{3})	24 mg x 0.625 = 15.1 mg	9.2 mg x 5 = 46.0 mg
Meat (250 g CO treated)	0.025 mg	0.025 mg

Sørheim, et al. (1997), p. 311, Table 5.

Part of the authors' analysis was the premise that absorption of CO from the gastrointestinal tract into blood will in all probability be less effective than absorption from the lungs. The authors summarized the comparison as follows:

> In order to prevent a maximum COHb level in the blood of 1.5% being exceeded, the CO concentration in air for a 1h period of moderate physical activity should not exceed 24 mg/m^3, or 9.2 mg/m^3 in 8h (according to Table 4). In contrast, the consumption of meat that had been treated for 3d in an atmosphere containing 1% CO yielded ~0.1 mg of CO per kg of meat on storage and cooking.

Sørheim, et al. (1997), p. 310, citing Watts, D.A.; Wolfe, S.K.; Brown, W.D., "Fate of [^{14}C]Carbon Monoxide in Cooked or Stored Ground Beef Samples", *J. Agric. Food Chem.*, Vol 26, No. 1 (1978), pp. 210-214.

The authors calculate that CO intake in 1h through the lungs taking in 15m^3 per day would result in 15.1 mg of CO, as compared with 0.025 mg of CO from intake of 250 g of CO treated meat. In 8 hours, the authors say the lungs will take in 46.0 mg, and the figure for meat would still be 0.025 mg. As the authors conclude,

> Estimates detailed above indicate that, even assuming an improbable 100% absorption of CO from the gastrointestinal tract into the blood, the consumption of meat that has been treated with 1% CO will result in COHb levels that are negligible (approximately 3 orders of magnitude lower) compared with those resulting from exposure in the working environment to CO at an acceptable level. Consequently, it is highly improbable that CO exposure from meat packaged in an atmosphere containing up to 0.5% will represent a toxic threat to consumers through the formation of COHb.

Sørheim, et al. (1997), p. 310.

In another published report, the storage life and characteristics of meats packaged in a modified atmosphere including 0.4% CO were studied, but under circumstances distinguishable from AT2001. Sørheim O; Nissen, H; Nesbakken, T, "The Storage Life of Beef and Pork Packaged in an Atmosphere With Low Carbon Monoxide and High Carbon Dioxide", 52 Meat Science 157-164 (1999). In the study, the meats were packed in

modified atmosphere into retail-ready packages. This study examined off odor and microflora, as well as color, comparing the 0.4% CO/ 60% CO_2 /40% N2 gas mixture with a gas mixture of 70% oxygen and 30% CO_2.

Among the points made by these authors was that there is sometimes an objection raised against using CO in retail ready meats because "the colour stability can exceed the microbiological shelf life, with the risk of masking spoilage of the meat." Sørheim, et al. (1999), p. 163. (Citing Kropf, D.H. (1980), "Effects of retail display conditions on meat colour", *Proceedings of the Reciprocal Meat Conference, 33, pp. 15-32.*) The authors assert that in those circumstances, consumers would need to rely on off odors to evaluate microbiological conditions of meat. In addition, they caution, "When a MA with CO is applied commercially, it is important to have a proper control of hygienic condition of the meat raw materials and the chill chain temperatures." See Sørheim, et al. (1999), p. 163.

AT2001, by contrast, presents no such similar problems or needs for caution. AT2001 does not mask spoilage of the meat. AT2001 does not involve use of a modified atmosphere including CO in the retail package. Moreover, as noted below, Pactiv's own commissioned experimentation with AT2001 demonstrates that AT2001 retail packages will deteriorate in color beginning almost immediately after removal of the modified

atmosphere, and that microbial load will not reach unsafe levels while the color of AT2001 meat is still acceptable to the consumer.

Safety: The Norwegian experience

In Norway, CO has been used to package fresh meats, even at retail, since 1985, with commercially satisfactory and safe results.

The 2000 submission by the Norwegian Meat Cooperative and Norwegian Independent Meat Association to the EU Commission seeking Europe-wide approval of the use of CO, "Application For Assessment Of The Food Additive Carbon Monoxide (CO) Prior To Its Authorization", is Attachment 3. The evaluation undertakes a detailed analysis of the CO exposure expected through the described packaging use. See section entitled "IV. Report by Tore Aune: "Fresh Meat in Consumer Packaging-A Toxicological Evaluation of the Use of Up to 0.5% CO in a Gas Mixture".

As the Norwegian risk assessment analysis concludes, assuming a worst-case exposure of 0.1 mg/kg from consumption of 250 grams of heated CO-treated meat, CO intake can be expected to be 0.025 mg in 1 hour or even after 8 hours. Attachment 3, p. 000154. The cited study, Sørheim, et al. (1997), utilized meat that had been treated with 1% CO. According to the authors, to stay under maximum blood levels of carboxyhemoglobin of 1.5%, "the CO concentration in the air must be 24

milligrams per mg/m^3 for 1 hour at moderate physical activity at 9.2 mg/m^3 for 8 hours...." Attachment 3, p. 000154. Assuming an adult inhales 15 m^3 per 24 hours, this translates to 15.1 mg of CO taken in 1 hour, or 46.0 mg of CO taken in 8 hours. This is in dramatic contrast to the miniscule amount expected to be ingested through meat. The Norwegian authors conclude, "From a health perspective, the use of CO in concentrations below 0.5-1% for fresh meat thus represents no toxicological risk." Attachment 3, p. 000155.

Safety: Exposure in environment

As a basis for comparison, the possible effect on ambient CO concentration associated with the release from a typical AT2001 barrier bag was estimated. A typical AT2001 barrier bag contains approximately 1.5 liters of modified atmosphere with a CO concentration of 0.4 percent, which is equivalent to approximately 0.006 liters of CO within the bag. On a mass basis, this volume of CO is equivalent to approximately 0.0075 g (7.5 mg) CO per bag.

Consider the possible use of the bag for storage of meat prior to retail display (e.g., at a supermarket). Any unassociated CO within the bag, it can be assumed, would be released to the meat processing area when the bag is opened, resulting in possible exposure by the employee(s) to the

released CO. The extent of such exposure is dependent on several factors, including the size of the meat processing area, air-mixing within the area and between adjacent areas, the number of bags opened, and the amount of free CO unassociated with the meat in the package. For these calculations, it has been conservatively assumed that none of the CO has become associated with the meat and is therefore all free to the ambient atmosphere upon opening of the package.

Assume, however, that the air volume within a meat processing area may reasonably range from 150 m^3 to 1,500 m^3, which would represent several hundred to several thousand square feet of processing area. If each bag introduces 7.5 mg CO to the air within the processing area, the corresponding concentration of CO in air would be in the range of 0.005 mg/m^3 to 0.05 mg/m^3, assuming conservatively that there is no air exchange between the processing area and other rooms or the outdoors. Thus, to exceed the occupational safety standard (i.e., threshold limit value, or TLV) of 25 ppm (29 mg/m^3), 580 to 5,800 1.5 liter bags would need to be opened within an 8-hour period. As noted above, this assumes no mixing with other areas of the building or with outdoor air.

Thus, applying the reasonable assumption that the air volume within the processing area will be exchanged with external air once per hour,

opening of 580 to 5,800 bags per hour would be required to exceed the TLV, or 4,600 to 46,000 bags per work day. The number of bags opened within a given processing area will be a function of the size of the processing area, to a given extent, but is unlikely to even approach the number of bags required to result in air concentrations at the TLV. Actual concentrations in the work area of a secondary processing facility would likely be one to two orders of magnitude below the standard. Thus, opening of bags within a work area will not alter significantly the environmental exposure to CO.[3]

Regardless, the opening of the bags does not alter significantly the environmental exposure to CO. This action qualifies for a categorical exclusion from preparation of an environmental assessment pursuant to 21 CFR Sec. 25.32 (i), which provides an exemption for, in pertinent part, "Approval of a ...GRAS affirmation petition...." 21 CFR Sec. 25.32(i). The regulation makes no specific mention of the GRAS Notice procedure, but similar treatment is warranted for a GRAS Notice. (We also note that CO as used here also qualifies for exclusion under 21 CFR Sec. 25.32(r), as CO "occurs naturally in the environment" and the noticed use "does not alter significantly the concentration or distribution of the substance, its

[3] As an aside, there is no reason to expect any difficulty achieving compliance with the OSHA Threshold

metabolites, or degradation products in the environment." 21 CFR Sec. 25.32(r).)

Corroborative information about AT2001

The specific AT2001 system has been thoroughly tested to confirm that it results in the expected limited exposures to CO, and has no adverse effects on the treated meats. A study of meats treated with AT2001 commissioned by Pactiv examined its effects on initial product color, stability of color during display, and the central safety consideration of the relationships between color deterioration and microbial populations.

The study, conducted by faculty of the Department of Animal Sciences & Industry of Kansas State University, Manhattan, Kansas, examined steaks from three cuts of beef (strip loin, tenderloin, and inside round steaks), as well as ground beef. The study report is Attachment 4. The meats were packaged in AT2001 atmosphere, then stored at 35° F or 43° F for up to 35 days. Cuts were then placed under simulated retail conditions by being removed from the AT outer package and displayed at 34° F until their color approached consumer unacceptability. Comparisons

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Limit Value at plants using the AT2000 technology to fill bags. Experimental use of an exhaust hood over the machinery has resulted in no measurable increase in CO ppm levels near the line.

were made to similar products that had been exposed to oxygen but not CO.

Among the study's conclusions were:

(1) Color: AT2001 *system resulted in products that were equally red to products packaged with traditional oxygen permeable overwrap.* When the AT2001 outer bag was removed, the product's conversion to oxymyoglobin occur red in 60-90 minutes and then had a typical bright red color. Visual appearance was improved, especially in the tenderloin and inner part of the inside round steaks, throughout display. Color deterioration compared well to baseline products exposed to oxygen. For tenderloin and inside round steaks, and to a lesser degree for ground beef, display time was increased only slightly in the AT2001 samples.

(2) Bacterial growth: Bacterial growth was neither encouraged nor suppressed by the addition of CO to the ActiveTech™ *gas blend (nitrogen and carbon dioxide),* although microbial growth curves changed in slope and exponential growth according to the environment in the packages. Aerobic bacteria and facultative anaerobes followed typical patterns of growth according to environmental conditions.

(3) Spoilage indicators: CO neither masked spoilage, nor extended color life beyond the point of wholesomeness (i.e., the point of microbial soundness).

A summary of the study follows.

A random selection of all steaks and ground beef packaged using oxygen-permeable polyvinyl chloride ("PVC") film were placed in display to serve as a baseline for color and microbiological comparisons. Products were expected to have the lowest microbiological load and ideal color stability using traditional packaging and display conditions for products exposed only to atmospheric oxygen. The inherent muscle chemistry responsible for good color life also was optimal. If the product exposed to CO were to have extended meat color life, then it will be compared to the baseline "control" with the "best" possible color.

To measure color changes, visual scores were considered the "standard" with instrumental color being discussed relative to its agreement or disagreement with the visual panel, ie, did the objective measurements confirm what the color panel saw? Visual scores of ≥ 3.5 were considered borderline acceptable. When samples reached this discoloration, they were removed from display. Normally, a* values (higher values indicate more redness) are highly correlated to visual appraisal.

Inside round steaks typically are two-toned in color. The inner portion (ISM) is much less color stable than the outer portion (OSM). These portions were scored separately since one portion may have acceptable color while the other has unacceptable color that would be discriminated against by consumers resulting in the whole cut being judged unacceptable in color. The effects of CO on this bi-colored muscle were needed to confirm that color was not excessively extended in either portion.

Average fat and moisture contents of the ground beef were 19.5 and 61.6%, respectively. The pH of both intact muscles and the ground beef ranged from 5.3 to 5.7. The initial aerobic plate counts and lactic bacteria counts for all products were relatively low and indicative of good microbial quality of the raw materials and good sanitation. Furthermore, coliforms and *E. coli* were below the detection limit throughout the study.

The color of ground beef and steaks entering display (after MAP storage at 2 temperatures) was an attractive, typical red color. Although there were several significant differences in visual scores and a* values (Attachment 9, Table 2 and Figures 1-10 at day 0) for product CO vs. baseline cuts, the variation in color was usually within $\pm$ 0.5 of a color score.

Color results: In general, the initial color of product exposed to CO was very similar to the color of steaks from the baseline display (never exposed to CO). When differences occurred, they were more related to either storage temperature or postmortem age of the product.

Panelists did not consider the color of product exposed to CO atypical. Cuts exposed to CO generally appeared more uniformly bright-red and would be expected to have high consumer appeal. These results were expected, as CO is known to preferentially form a ligand with the colored pigment (myoglobin) in meat resulting in a more intense red pigment known as carboxymyoglobin.

In the AT2001 system, Pactiv uses a low level of 0.4% CO, and obtains a red color very similar to the normal red oxymyoglobin pigment of fresh meats exposed to oxygen.

Color stability results: A critical next question was whether the carboxymyoglobin formed on the surface was more stable than the oxymyoglobin formed in baseline product. Further, did the carboxymyoglobin deteriorate in a predictable way that consumers could continue to use visual color to judge freshness or potential spoilage?

Product exposed to CO during MAP storage had color deterioration during display. (See visual panel scores (Attachment 4, Figures 1-5) and

instrumental color (a^* values, Attachment 4, Figures 6-10).) As expected, visual scores increased (color deteriorated) and a^* values decreased (loss of redness) as days in display increased. In several instances, color appeared to improve late in display – as indicated by a decrease in visual scores (see ground beef, strips loins and tenderloins at 43°F). These decreases were not a return of redness, but resulted from removal of discolored packages the preceding period, leaving product with less overall discoloration remaining in the case.

In general, the color deterioration profiles followed an expected pattern. Namely, the freshest product (baseline packages) had the most stable, red color and the most days in display needed to reach borderline discoloration of all treatments. (Attachment 4, Table 3 scores to 3.5) Exceptions occurred for the inside portion of the inside round and tenderloin products, where the product exposed to CO had slightly more stable color than the baseline product (Attachment 4, Table 3). These two muscle areas are well known by retailers as having short color life. Thus, CO appeared to improve color life when the inherent muscle chemistry desired for color was limited.

For product from MAP, the longer the storage time, the faster the deterioration, especially at the higher storage temperature (Attachment 4,

Tables 2 and 3). For packages stored at 43°F, which was a mildly abusive temperature, color deterioration would be expected to accelerate. This phenomenon also is illustrated in Attachment 4, Figures 1-10.

There was no evidence the color shelf life was unexpectedly lengthened by exposure of meat to CO in MAP. Changes in a* values (and other instrumental measures of color not shown) followed the same pattern of color deterioration observed by the visual panelists.

Color and microbial data: Initial, pre-display microbiological data suggested that the raw materials were fresh and processed using good hygienic practices. For intact cuts, lactic acid bacteria, generic *E. coli*, and total coliform counts were below the detection limit of 1.76 colony forming units (CFU)/in^2. Initial, pre-display aerobic plate counts ("APC") for intact muscles ranged from 1 to 1.63 $\log_{10}$ CFU/in^2. Post-display counts were higher ($P<0.05$) than pre-display APC which was an increase in bacterial proliferation and typical deterioration. However, all product had sufficient microbes to be susceptible to spoilage.

Baseline products were pulled from display when the visual panel scores reached ≥ 3.5. However, the APC did not exceed 5 $\log_{10}$ CFU/unit as shown in Attachment 4, Figures 15-18. Furthermore, off-odor scores for

product at end of display (Attachment 4, Table 3) ranged from no to slight off odor.

Thus, color life in this base population did not exceed microbial soundness, which is generally accepted as < 100 million CFU/g hamburger ($<1 \times 10^8$). (Principles of Meat Science, 3d Ed., Hedrick, H.B.; Aberle, ED, Forrest, JD; Judge, MD; Merkel, RA, Eds, Kendall/Hunt Publishing Co., Dubuque, Iowa.

Similar trends in microbial growth occurred in post-displayed samples stored in MAP compared to baseline products. Microbial patterns for product deterioration are shown in Attachment 4, Table 4 and Figures 11-18. Products stored under MAP at a slightly abusive temperature showed, as expected, a more rapid increase ($P<0.05$) in microbial counts compared to samples stored at 35°F. For post-MAP (pre-display) and post-display samples, APC were higher at 45°F than 35°F (Table 4), and during the later days of storage at the higher temperature, differences were more obvious. Significant changes ($P<0.05$) occurred in all cuts and ground beef with the exception of semimembranosus muscle. Counts for the SM muscle were lower than expected and no significant changes occurring until day 35 of MAP storage. This suggests that quality products that have been handled

in a sanitary fashion can be stored in the AT2001 system up to 35 days without comprising microbial quality.

The APCs for intact strip loin and tenderloin steaks stored at 35°F were lower ($P<0.05$) on all days of display on days 21 and 35 post-MAP than steaks stored at 43°F (Attachment 4, Figures 12 and 14). Although products did not show a difference in APCs 7 days post-MAP, those products stored at the higher temperature (43°F) were more inferior 21 and 35 days post-MAP.

One goal of this research was to see if the color of CO-treated meat might mask spoilage. Visual color scoring was considered as the "standard" for determining the time to remove products from display. Because the visual panel scores were the deciding factor for length of shelf life, the interdependence between visual color and APC, LAB, and odor were considered quite important.

Attachment 4, Figures 19-21 show aerobic and lactic bacterial growth and odor scores at the end of display plotted against their corresponding visual color scores. All data observations were summed over storage temperature, storage time, and product type and plotted in one graph. If color masked spoilage, then there would be multiple points in the upper left

quadrant of the plot, the area represented by unacceptable microbial counts and off odors but with acceptable color (i.e., scores <3.5).

This did not occur with any frequency in any of the three plots. Thus, it does not appear that exposure of meat to CO during extended (up to 35 days at either 35° or 43°F) caused meat color to hide spoilage.

e. Statement of availability of information

Notifier has relied on published studies and generally accepted scientific data and information as the basis of its conclusions, and those of its panel of experts, about the safety and the general recognition of a modified atmosphere system for meat incorporating 0.4% CO in the gas mixture.

II. Identity of notified substance

1. Chemical name: Carbon monoxide
2. Chemical Abstracts Service: **630-08-0**
3. Composition Specifications for food-grade material: The CO employed in this system is to be of suitable purity for food contact. Specifically, this will mean a 99.99% minimum purity, as supplied by Pactiv's commercial gas supplier, Haun Welding Supply, Inc., 6481 Ridings

Road, Syracuse, NY 13206. Attachment 5. The supplier's CO meets the following specifications, and will be referred to as "commercial grade":

Component	Specification
Carbon Monoxide	99.99% min.
Oxygen	≤ 0.5 PPM
Nitrogen	≤ 10 PPM
Carbon Dioxide	≤ 20 PPM
Methane	≤ 5 PPM
Ethane	≤ 1 PPM
Propane	≤ 1 PPM
Dimethyl Ether	≤ 1 PPM
Hydrogen	≤ 1 PPM
Moisture	≤ 1 PPM

4. Properties:

Relative molecule mass	28.01
Critical point	−140.2 °C at 34.5 atm (3.5 MPa)
Melting point	−205.1 °C
Boiling point	−191.5 °C
Density, at 0 °C, 1 atm	1.250 g/litre
at 25 °C, 1 atm	1.145 g/litre
Specific gravity relative to air	0.967
Solubility in water at 0 °C, 1atm	3.54 ml/100 ml
at 25 °C, 1 atm	2.14 ml/100 ml
at 37 °C, 1 atm	1.83 ml/100 ml[a]
Conversion factors:	
at 0 °C, 1 atm	1 mg/m^3 = 0.800 ppm[b]
	1 ppm = 1.250 mg/m^3
at 25 °C, 1 atm	1 mg/m^3 = 0.873 ppm
	1 ppm = 1.145 mg/m^3

[a] Value obtained by graphic or calculated interpolation (Altman et al., 1971).
[b] Parts per million by volume

5. Analyses: ASTM D1946, "Analysis of Reformed Gas by Gas Chromatography (GC) with Thermal Conductivity Detection (TCD)", may be utilized to measure the quantity of CO present in gas mixtures. A copy of the method is Attachment 6.

III. Self-limiting levels of use

Studies of modified atmospheres for packaging meat that contained both higher and lower levels of CO have established that the 0.4% used in the AT2001 system both has advantageous characteristics and avoids disadvantages seen with lower or higher levels. A CO level of 0.4% is sufficient to produce stable, cherry red color, (Sørheim, et al. (1997), and use of CO through retail display time may result in masked spoilage.

IV. Basis of GRAS determination.

Pactiv believes its use of CO is GRAS based on scientific procedures, 21 CFR Sec. 170.30(b), and convened a panel of experts qualified by scientific training and experience to evaluate the safety of food, food additives and food ingredients. The experts have reviewed and evaluated the publicly available information summarized in this GRAS Notice. Their testimonial

letters are attached as Attachments 7 through 10. The above discussion and citations to generally available accepted scientific data, information, methods and principles relied upon, together with the anticipated consumption levels for both CO and meat treated with CO, provide ample basis to conclude that the use of CO at 0.4% in a modified atmosphere for packaging fresh meats is both safe and generally recognized as such by qualified experts.

The panel consisted of the following experts, whose GRAS opinions and curricula vitae are attached as attachments 7 through 10.

1. Daren Cornforth, Ph.D.
   Professor
   Department of Nutrition and Food Sciences
   Utah State University
   750 N. 1200 E.
   Logan, Utah 84322-8700

Dr. Cornforth is a professor in Nutrition and Food Sciences at Utah State University, Logan, Utah, and received his Ph.D. in food science and human nutrition from Michigan State University. He has performed extensive research and published multiple articles on the subject of meat color.

2. Vasilios Frankos, Ph.D.
   Principal
   Environ Corp.
   4350 N. Fairfax Dr.

Suite 300
Arlington VA 22203

Dr. Frankos is a Principal at ENVIRON corporation, Arlington, Virginia, a scientific consulting firm, and has over 20 years of experience in the toxicological and pharmacological evaluation of data used to assess the risks posed by foods, food additives, and other substances. He holds a Ph. D. from the University of Maryland Pharmacy School in Pharmacology and Toxicology.

3. Melvin C. Hunt, Ph.D
Professor
Weber Hall
Dept. of Animal Sciences and Industry
Kansas State University
Manhattan, KS 65506

Dr. Hunt is a professor of food science at the Department of Animal Sciences and Industry at Kansas State University, Manhattan, Kansas. He received his Ph.D. in food science at the University of Missouri. Among his many research projects and publications are multiple studies relating to meat color and the effects of various environments on meat color.

4. Oddvin Sørheim, Ph.D.
Senior Research Technologist
MATFORSK – Norwegian Food
Research Institute
Osloveien 1

N-1430 Ås
Norway

Dr. Sørheim is a Senior Research Technologist at the Norwegian Food Research Institute, Osloveien, Norway. He received his Ph.D. in food science from the Agricultural University of Norway, and has performed extensive research and industry consultation, and published numerous articles on meat, including extensive experience with the use of CO in modified atmosphere packaging of meat.

Pactiv is not aware of any reports of investigations that are inconsistent with the GRAS determination relating to the use described.

Conclusion

Based on all the above information, Pactiv Corporation has concluded that its use of 0.4% CO within the AT2001 modified atmosphere system for packaging fresh meat is Generally Recognized as Safe within the meaning of 21 U.S.C. Sec. 321(s).

Sincerely,

Eric F. Greenberg

K-STATE
Kansas State University
Animal Sciences and Industry
K-State Research and Extension
232 Weber Hall
Manhattan, KS 66506-0201
785-532-6533
Fax: 785-532-7059

August 8, 2001

Eric F. Greenberg
Of Counsel
Ungaretti & Harris
3500 Three First National Plaza
Chicago, IL 60602-4283

Dear Mr. Greenberg:

The purpose of this letter is to confirm that I believe the use of a small quantity of carbon monoxide in the modified packaging system know as ActiveTech (by PACTIV) is safe and should qualify as GRAS. I have been a research meat scientist for nearly 30 years and have focused most of that time on factors affecting meat color and shelf life, including packaging systems. Thus, I am familiar with most of the world literature on such systems.

Based on my review of the details of the ActiveTech 2001 modified atmosphere system employing 0.4% carbon monoxide gas in a mixture with 60 percent carbon dioxide and the remainder nitrogen, as well as the published literature and common knowledge in the field, I am confident that the use of modified atmosphere including small quantities of carbon monoxide (0.4%) to package fresh meats as used in ActiveTech 2001 system is both safe and generally recognized as safe.

Sincerely,

Melvin C. Hunt

Melvin C. Hunt
Professor

ELSEVIER

Meat Science 52 (1999) 157–164

MEAT SCIENCE

The storage life of beef and pork packaged in an atmosphere with low carbon monoxide and high carbon dioxide

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Received 13 February 1998; received in revised form 28 October 1998; accepted 1 December 1998

Abstract

Ground beef, beef loin steaks and pork chops were packaged in modified atmospheres of 0.4% CO/60% CO_2/40% N_2 and 70% O_2/30% CO_2. In addition ground beef was packaged in clipped chub packs, beef loin steaks were vacuum packaged, and pork chops were packaged in an atmosphere of 60% CO_2/40% N_2 with each pack containing an O_2 absorber. The packs were stored in the dark at 4 or 8°C for up to 21 days. Meat in 0.4% CO/60% CO_2/40% N_2 had a stable bright red colour that lasted beyond the time of spoilage. The storage lives in this gas mixture at 4°C, as limited by off-odours, were 11, 14 and 21 days for ground beef, beef loin steaks and pork chops, respectively. The 70% O_2/30% CO_2 atmosphere resulted in an initially bright red to red colour of the meat, but the colour was unstable and off-odours developed rapidly. The off-odours probably were caused by *Brochothrix thermosphacta*, which grew in all meat types, or by pseudomonads in ground beef. Meat stored in chub packs, vacuum packs or 60% CO_2/40% N_2 with an O_2 absorber developed off-odours and microflora similar to those of meat in 0.4% CO/60% CO_2/40% N_2, but with less acceptable appearances. These results show that a low CO/high CO_2 atmosphere is effective for preserving retail-ready meat.

1. Introduction

The main reasons for modified atmosphere packaging (MAP) of red meats for retail sale are to prolong the microbiological shelf life and to maintain an attractive red colour of the product. Modified atmospheres (MA) usually consist of carbon dioxide (CO_2) for inhibiting microbiological growth, oxygen (O_2) for enhancing colour and, occasionally, nitrogen (N_2) as a filler. The most common gas mixture for retail-ready meat contains approximately 70% O_2 and 30% CO_2, and gives the product an extended shelf life compared to air (Gill, 1996). The shelf life and colour stability of meat stored in this gas mixture is still limited. To obtain a stable red colour for the meat, low concentrations (< 1%) of carbon monoxide (CO) can be introduced in the MA. Then, O_2 can be removed from the gas mixture and the concentration of bacteriostatic CO_2 can be increased. Anaerobic conditions extend the shelf life of meat considerably compared to air and O_2-enriched atmospheres (Gill & Molin, 1991). CO binds strongly to the meat pigment myoglobin to form stable carboxymyoglobin which has a cherry red colour (El-Badawi, Cain, Samuels, & Angelmeier, 1964). Low concentrations of CO have little effect on the microflora of meat (Clark, Lentz, & Roth, 1976; Gee & Brown, 1978; Luño, Beltrán, & Roncalés, 1998).

The Norwegian meat industry has for the past decade been using a gas mixture of approximately 0.3–0.5% CO, 60–70% CO_2 and 30–40% N_2 in retail-ready packages of beef, pork and lamb. Packages with this gas mixture now have a 50–60% share of the domestic, retail, red meat market. The technological, hygienic and toxicological aspects of using CO in MA for meat have recently been reviewed with the conclusion that CO used in concentrations up to 1% does not present a toxic hazard to the consumer (Sørheim, Aune, & Nesbakken, 1997a). However, CO may mask spoilage, because the stable cherry red colour can last beyond the microbiological shelf life of the meat (Kroof, 1980).

The inclusion of CO in MA for meat is controversial. CO is presently not allowed in MA for meat in the USA and in the EU (Cornforth, 1994; European Parliament and Council Directive, 1995). However, Norwegian food control authorities have up to now not opposed

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the use of up to 0.5% CO in MA for meat. This would change with an adoption of EU food regulations in Norway. Consequently, the Norwegian meat industry is seeking amendments of current EU food regulations relating to the use of CO in MAP of red meats. If the use of CO should be disallowed, other means of maintaining the long shelf life and the attractive red colour of the meat will have to be sought.

The aim of the present experiments was to compare a commercial Norwegian $CO/CO_2/N_2$ mixture with alternative gas mixtures and packaging methods for their effects on the off-odour, microflora and colour of ground beef, beef loin steaks and pork chops stored at 4 or 8°C for up to 21 days.

2. Materials and methods

2.1. Preparation of meat

2.1.1. Ground beef

Twenty cow and bull carcasses of Norwegian Red Cattle, which weighed on average 275 kg, were electrically stimulated with 90 V and were chilled using programmed air temperatures between 12 and −5°C. Two days after slaughter the carcasses were deboned, and trimmings with 14% fat were ground through a 4 mm plate. The batch of ground beef was divided into 500 g portions.

2.1.2. Beef loin steaks

Loins (*m. longissimus lumborum et thoracis*) with ultimate pH values below 5.8 were deboned from 25 bull carcasses of Norwegian Red Cattle. These carcasses, which weighed on average 275 kg, were stimulated, chilled and deboned the same way as the carcasses used in the preparation of ground beef. The loins were vacuum packaged and aged for 11 days at 3°C. Thereafter, the loins were cut into steaks 2.5 cm thick, and were randomly assigned to retail packs which each contained two steaks.

2.1.3. Pork chops

Thirty pig carcasses of Norwegian Land Race, which weighed on average 75 kg, were blast-chilled. Four days after slaughter, bone-in loins were removed and crust-frozen in liquid N_2 at −50°C for 20 min to facilitate cutting of chops. The chops, which were 1.6 cm thick, were randomly assigned to retail packs which each contained two chops.

2.2. Packaging

Ground beef, beef loin steaks and pork chops were packaged in 0.4% CO/60% CO_2/40% N_2 (CO mixture) and 70% O_2/30% CO_2 (high O_2). In addition, ground beef was packaged in clipped chub packs, beef loin steaks were vacuum packaged and pork chops were packaged in 60% CO_2/40% N_2 with one Ageless® FX-100 O_2 absorber (Mitsubishi Gas Chem. Co. Inc., Tokyo, Japan) in each pack (mixture with O_2 absorber).

The meat was packaged at a commercial meat plant within 2 h of grinding or cutting. Meat in the CO mixture, the high O_2 mixture and the mixture with O_2 absorber was packaged in an Ilapak Delta 2000 flow-packaging machine (Ilapak Machine Auto S.A., Grancia, Switzerland). The CO mixture was a blend of 1% CO/99% N_2 with 100% CO_2. The high O_2 mixture was used as a preblend. The mixture with O_2 absorber was a blend of 100% N_2 with 100% CO_2 (all gases, Hydrogas, Porsgrunn, Norway). The initial gas volume to meat weight ratio in the packs was approximately 1.5 to 1. The packs consisted of polyethylene trays (Færch Plast, Holstebro, Denmark) wrapped in Cryovac BDF 550 shrinking film (Cryovac, Milan, Italy) with an O_2 transmission rate of 19 $cm^3/m^2/24$ h/atm at 23°C and 0% RH. Chub packs of ground beef were packaged in a clipping machine (Poly-Clip, Frankfurt, Germany) using a red, fishingnet-patterned, polyethylene film (SFK, Vidovre, Denmark) with an O_2 transmission rate of 500 $cm^3/m^2/24$ h/atm at 23°C and 0% RH. Beef loin steaks were vacuum packaged in a Multivac 5100 thermo-forming machine (Multivac, Wolfertschwenden, Germany) using a terephtalate/polyethylene upper film and polyamide/polyethylene lower film with O_2 transmission rates of 10 and 16 $cm^3/m^2/24$ h/atm at 23°C and 0% RH, respectively (Danisco, Horsens, Denmark).

2.3. Storage and sampling of meat

Five samples were collected from the ground beef batch, beef loins and pork loins before packaging, for pH measurements and microbiological analyses.

The packaged meat was stored in dark chilling rooms at 4 ± 0.5 or 8 ± 0.5°C for up to 21 days at least until off-odours developed. Five packs were removed per product, packaging method, storage temperature and sampling day after the following storage times:

- ground beef: 2, 4, 6, 8 or 11 days;
- beef loin steaks: 3, 7, 10 or 14 days; and
- pork chops: 3, 7, 10, 14, 17 or 21 days.

2.4. Gas analyses

The atmospheres of packs with MA were analysed for O_2 and CO_2 immediately after packaging (approximately every tenth pack) and at sampling (all packs). O_2 was determined using a Toray LC 700-F gas analyser (Toray Engineering, Osaka, Japan) and CO_2 using a Toray PG-100 gas analyser (Toray). The threshold levels for the O_2 and CO_2 analyses were 0.05 and 1%, respectively. Gas samples of 10 cm^3 were removed with a syringe through selfsealing patches on the packs.

2.5. pH

The pH measurements were made directly in the meat with an Ingold Xerolyt gel electrode (Mettler-Toledo A.G., Greifensee, Switzerland).

2.6. Odour

The meat was evaluated for odours by a three member trained panel between 0.5 and 1 min after opening of the packs. The off-odour scale used was: 1 = none, 3 = slight and 5 = extreme. Scores of 3 or below were considered acceptable.

2.7. Microbiology

Ten gram meat samples were collected from portions of the ground beef, and diluted in 90 g peptone water. A sample 25 cm^2 and 2–3 mm thick was removed from the surface of each beef loin or steak and pork loin or chop with a scalpel, and diluted in 100 ml peptone water. Each sample was macerated in a Stomacher for 1 min. Serial 10-fold dilutions of each Stomacher fluid were prepared, and 20 μl volumes of appropriate dilutions were plated in duplicate on the following media:

- plate count agar (PCA; Difco, Difco Laboratories, Detroit, MI, USA) for total viable counts;
- de Man, Sharpe and Rogosa agar (MRS; Oxoid, Unipath Ltd., Basingstoke, Hampshire, UK) adjusted to pH 5.7 for lactic acid bacteria (de Man, Rogosa, & Sharpe, 1960);
- streptomycin thallous acetate actidione agar base (STAA; CM 881 with selective supplement SR 151; Oxoid) for *Brochothrix thermosphacta*;
- pseudomonads agar base (CFC; CM 559 with selective supplement SR 103; Oxoid) for pseudomonads;

In addition, 1 ml portions of appropriate dilutions were plated in duplicate on petrifilm coliform count plates (3M Microbiology Products, St. Paul, MN, USA) for enumeration of coliforms and *Escherichia coli*.

Plates of PCA, MRS, STAA and CFC were incubated at 20°C for four days, and petrifilm plates at 30°C for up to 2 days, all aerobically. Counts were expressed as colony forming units (CFU) per g or cm^2.

2.8. Colour

A six-member trained panel evaluated the colour of the meat in intact packs under 1200 ± 200 lux Warmton Lumilux L36W/31 yellow–white light (Osram, Drammen, Norway). The colour was assessed on a scale where 1 = bright red (ground beef and beef loin steaks) or light bright red (pork chops), 2 = red (ground beef and beef loin steaks) or light red (pork chops), 3 = slightly brown, grey or green, 4 = moderately brown, grey or green and 5 = extremely brown, grey or green (National Live Stock and Meat Board, 1991).

A Minolta Chroma Meter CR-300 (Minolta Camera Co., Osaka, Japan) with 8 mm viewing port and illuminant D_{65} was used for measuring CIE a^* values (redness). The colour was measured directly at the meat surface within 1 min of opening of each pack.

Ground beef in chub packs was not included in the colour analyses because the red packaging film hides the colour of the product. With pork chops, the colour of only the *m. longissimus lumborum et thoracis* was analysed.

2.9. Statistics

Analysis of variance by Tukey's multiple comparisons test was performed using the Systat programme, version 6 (Systat Inc., Evanston, IL, USA).

3. Results

3.1. Gas composition

The initial O_2 concentrations in packs with the CO mixture and the mixture with O_2 absorber were all below 0.5% immediately after packaging. O_2 was not detected in these packs after 2 or 3 days storage. The level of O_2 in packs of high O_2 was reduced from the initial 70 to 60–65% during storage for up to 21 days. Concentrations of CO_2 in the packs were generally reduced by one fifth after 2 or 3 days storage, and were then stable (data not shown).

3.2. Storage life of ground beef

The time to develop off-odours was 2 to 3 days longer for ground beef stored in the CO mixture and in chub packs than in high O_2, and it was 4 or 5 days longer at 4 than at 8°C for all three packaging methods (Table 1). In high O_2, the total viable counts increased faster and were higher ($p < 0.01$) than for the other two types of packaging after 2 days at either 4 or 8°C [Fig. 1(a)]. The total viable counts were more than 90% lactic acid bacteria (data not shown). The high numbers of lactic acid bacteria in ground beef, up to approximately $\log_{10}$ 8 CFU/g, caused a decrease in the pH value from the initial 5.7 to 5.2 after 6 days when the meat was stored in the CO mixture or chub packs at 8°C (data not shown). At 4°C, the pH value was reduced to 5.5 after 11 days in both those packaging systems. The numbers of *B. thermosphacta* increased, in meat in high O_2 [Fig. 1(b)]. In meat in high O_2 the numbers of pseudomonads increased up to approximately $\log_{10}$ 7 CFU/g, but only to $\log_{10}$ 5 and 6 CFU/g in

meat in the CO mixture or chub packs, respectively (data not shown).

Ground beef in the CO mixture had a stable bright red colour, as shown by both the low colour scores and the high a^* values [Fig. 1(c) and (d)]. Meat in high O_2 was significantly less red ($p < 0.05$) than meat in the CO mixture, with higher colour scores and lower a^* values at day 2 and at later storage times at both 4 and 8°C. The colour of meat in high O_2 deteriorated with time, significantly faster ($p < 0.01$) at 8 than at 4°C.

Table 1
Time for development of off-odours in different types of meat in various packagings at storage temperatures of 4 or 8°C

Product	Packaging[a]	Time of off-odour detection (days)	
		4°C	8°C
Ground beef	CO mixture	11	6
	High O_2	8	4
	Chub packs	11	6
Beef loin steaks	CO mixture	14	7
	High O_2	10	7
	Vacuum packs	14	7
Pork chops	CO mixture	21	14
	High O_2	14	7
	Mixture with O_2 absorber	17	10

[a] CO mixture = modified atmosphere of 0.4% CO/60% CO_2/40% N_2; High O_2 = modified atmosphere of 70% O_2/30% CO_2; Mixture with O_2 absorber = modified atmosphere of 60% CO_2/40% N_2 with an O_2 absorber in the pack.

3.3. Storage life of beef loin steaks

At 4°C, off-odours developed 4 days later in beef loin steaks in the CO mixture and in vacuum packs than in high O_2 (Table 1). At 8°C, no differences in the development of off-odours were observed. Off-odours developed 4 to 7 days earlier in meat at 8 than at 4°C. The type of packaging did not significantly affect ($p < 0.05$) the total viable counts on the meat, but the counts were significantly higher ($p < 0.01$) at 8 than at 4°C after both 3 and 7 days of storage [Fig. 2(a)]. The numbers of *B. thermosphacta* were less than $\log_{10} 4$ CFU/cm^2 in meat in all types of packaging at all times, but were significantly higher ($p < 0.05$) on meat in high O_2 at 7 and 10 days than on meat in the CO mixture and in vacuum packs at equivalent times [Fig. 2(b)]. The numbers of pseudomonads did not exceed $\log_{10} 3.5$ CFU/cm^2 at any sampling time, and were not significantly affected ($p > 0.05$) by the type of packaging or the storage temperature.

The colour of the beef loin steaks in the CO mixture was stable bright red throughout storage at both 4 and 8°C, as shown by the low colour scores and high a^* values [Fig. 2(c) and (d)]. Steaks in high O_2 were also bright red with high a^* values at day 3, but these steaks discoloured gradually between days 3 and 10, significantly faster ($p < 0.05$) at 8 than at 4°C. Meat in vacuum packs was slightly discoloured with low a^* values throughout storage. The colour scores and a^* values of vacuum packaged steaks were not significantly affected ($p > 0.05$) by the storage temperature.

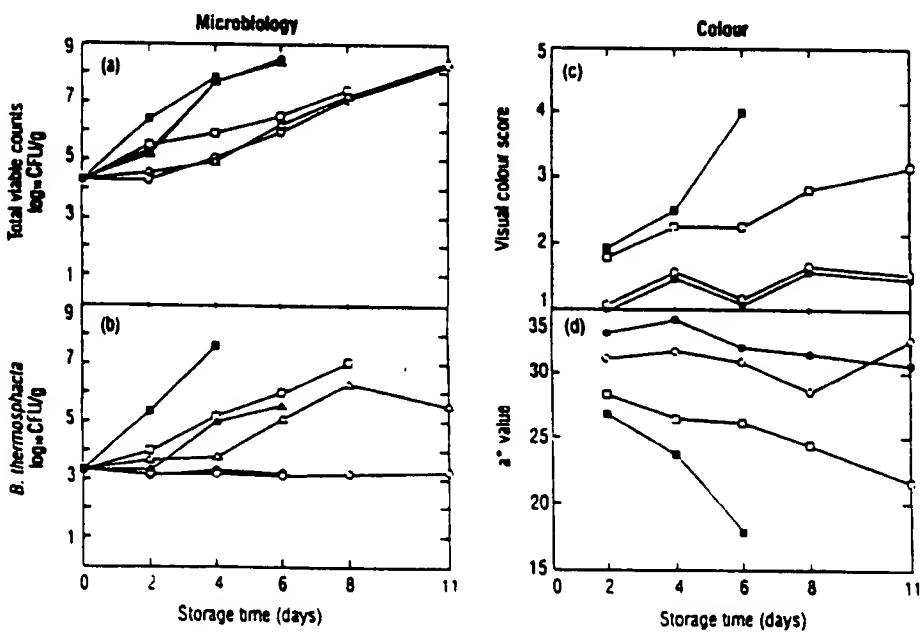

Fig. 1. Mean values ($n = 5$) for (a) total viable counts, (b) numbers of *Brochothrix thermosphacta*, (c) visual colour scores and (d) CIE a^* values for ground beef stored in 0.4% CO/60% CO_2/40% N_2 at 4°C (○) or 8° C (●), in 70% O_2/30% CO_2 at 4°C (□) or 8°C (■), or in chub packs at 4°C (△) or 8°C (▲). Colour was assessed on a scale where 1 = bright red and 5 = extremely discoloured.

3.4. Storage life of pork chops

For pork chops, off-odours developed more slowly in meat in the CO mixture than in meat in the mixture with O_2 absorbers or in high O_2 (Table 1). Off-odours were detected 7 days earlier at 8 than at 4°C for chops in each type of packaging. The type of packaging did not affect the total viable counts on the pork chops [Fig. 3(a)]. However, the counts were greater on meat stored at 8 than at 4°C. The numbers of *B. thermosphacta* on chops in high O_2 were significantly higher ($p < 0.01$) than on chops in the CO mixture or in the mixture with O_2 absorbers after 7 days at 8°C or 10 days at 4°C, and reached approximately $\log_{10}$ 6 CFU/cm^2 [Fig. 3(b)]. The numbers of pseudomonads did not exceed $\log_{10}$ 3 CFU/cm^2 on any of the pork chops.

The colour of pork chops in the CO mixture was light bright red with high a^* values throughout storage [Fig. 3(c) and (d)]. Chops in high O_2 were red at day 3, but discoloured during storage, significantly faster ($p < 0.05$) at

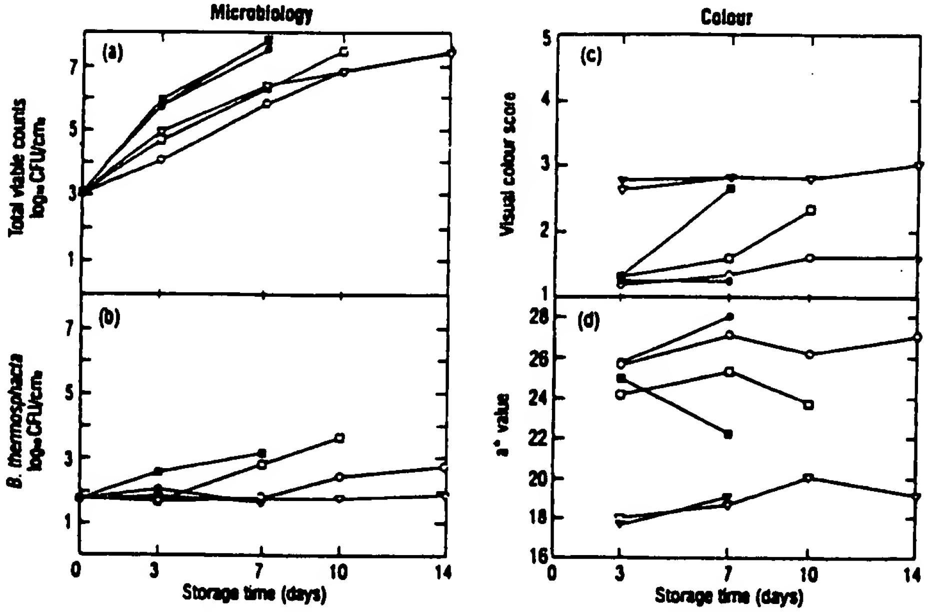

Fig. 2. Mean values ($n = 5$) for (a) total viable counts, (b) numbers of *Brochothrix thermosphacta*, (c) visual colour scores and (d) CIE a^* values for beef loin steaks stored in 0.4% CO/60% CO_2/40% N_2 at 4°C (○) or 8°C (●), in 70% O_2/30% CO_2 at 4°C (□) or 8°C (■), or in vacuum packs at 4°C (▽) or 8°C (▼). Colour was assessed on a scale where 1 = bright red and 5 = extremely discoloured.

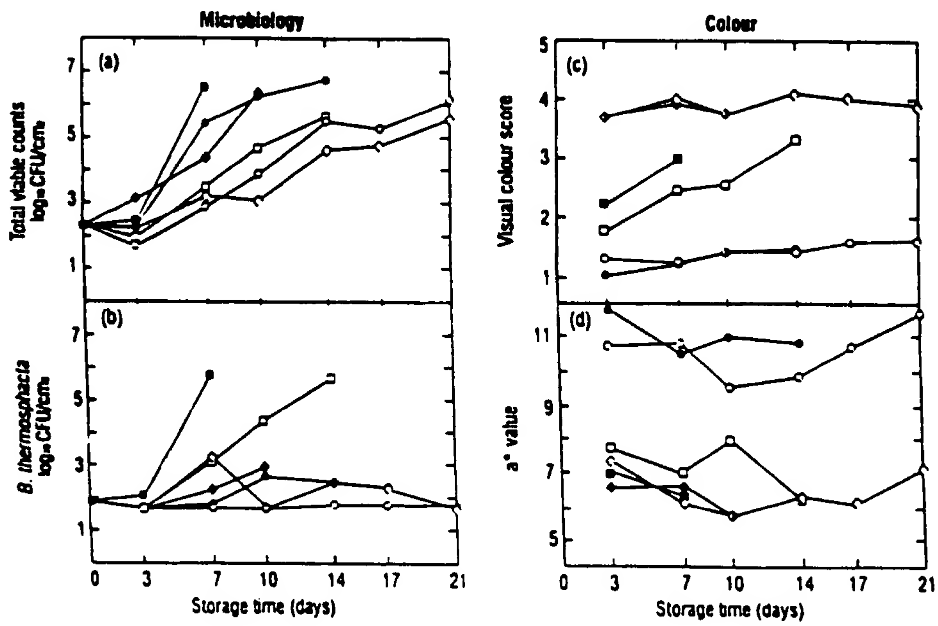

Fig. 3. Mean values ($n = 5$) for (a) total viable counts, (b) numbers of *Brochothrix thermosphacta*, (c) visual colour scores and (d) CIE a^* values for pork chops stored in 0.4% CO/60% CO_2/40% N_2 at 4°C (○) or 8° C (●), in 70% O_2/30% CO_2 at 4°C (□) or 8°C (■), or in 60% CO_2/40% N_2 with O_2 absorbers at 4°C (◇) or 8°C (◆). Colour was assessed on a scale where 1 = light bright red and 5 = extremely discoloured.

8 than at 4°C. Approximately 75% of the chops in high O_2 had black back bones at the time of sampling. Chops in the mixture with O_2 absorbers were moderately discoloured from day 3 to the end of storage. These chops had a^* values similar to those of chops in high O_2.

4. Discussion

4.1. Off-odour and microflora

The shelf life of the meat, as determined by the time to develop off-odours, was influenced by the packaging method, the storage temperature and the initial microbiological load on the meat. Storage of meat in the CO mixture, in vacuum packs or in chub packs gave the longest shelf lives. Meat stored in high O_2 generally developed off-odours 2–7 days earlier at 4 or 8°C than meat packaged in the other gas mixtures or by the other methods.

The differences in the rates of development of off-odours, as affected by the packaging method, were seldom related to any differences in numbers of total viable counts. However, the development of off-odours from the three meat types, especially ground beef and pork chops in high O_2, coincided with the attainment of high numbers of *B. thermosphacta*. For ground beef, storage in the CO mixture retarded growth of *B. thermosphacta* even more than storage in chub packs. At chill temperatures above 1°C, *B. thermosphacta* often causes spoilage of meat stored in high O_2 atmospheres (Dainty & Mackey, 1992). High concentrations of CO_2, removal of O_2 and low storage temperature inhibit the growth of *B. thermosphacta* (Gill, 1996; Nissen, Sørheim, & Dainty, 1996). Pseudomonads probably contributed to the off-odours of ground beef. Meat in high O_2 is often spoiled by *Pseudomonas* spp., but the growth of pseudomonads is retarded under anaerobic conditions (Dainty & Mackey, 1992; Gill, 1996). A shift in the metabolism of lactic acid bacteria under aerobic conditions can also produce off-odours (Nissen et al., 1996). In the present experiments, the numbers of coliforms or *E. coli* did not exceed $\log_{10}$ 3 CFU/g or cm^2 in any samples. Therefore, those organisms probably did not contribute to off-odours.

For pork chops, the effect of CO on the microflora can be evaluated because the gas compositions of the CO mixture and of the mixture with O_2 absorber were identical, except for the inclusion of 0.4% CO in the former. Although a 4 day increase in the time to develop off-odours was observed with the CO mixture, there was no significant reduction in the microbiological counts. Luño et al. (1998) used 1% CO in high O_2 atmospheres and noted a delay in the onset of off-odours without any reduction in the numbers of psychrotrophic bacteria. However, Clark et al. (1976) found that the addition of 0.5-10% CO to N_2 atmospheres reduced the number of psychrotrophic bacteria and increased the odour shelf life of beef. For example, 1.0% CO in 99% N_2 increased the time to develop off-odours at 5°C from 18 to 24 days. The lack of such an effect of CO on bacteria in our experiments may be due to the use of 60% CO_2 overshadowing any effect of CO.

The use of CO makes it possible to dispense with O_2 and so to increase the CO_2 concentration in a MA to about 60%. Our data suggest that 0.4% CO probably has little or no direct effect on the growth of bacteria. Other studies have shown that increasing the CO_2 concentration from 20 to 100% increases the bacteriostatic effect of the gas, but the efficiency is highly dependent on low storage temperatures (Gill & Molin, 1991; Nissen et al., 1996). The high CO_2 concentration and absence of O_2 in the CO mixture will favour the growth of lactic acid bacteria, which usually cause a mild form of spoilage only late in the development of the spoilage flora (Gill, 1996).

The present experiments were performed at acceptable and abusive storage temperatures to assess the effects of temperatures commonly encountered in the distribution and sale of retail-ready meat. The storage temperature strongly affected the rates of growth of microflora and the time to develop off-odours. Consequently, independently of the packaging method, the shelf life of meat can be considerably extended by maintaining low temperatures in the chill chain (Gill & Molin, 1991; Nissen et al., 1996).

4.2. Colour

The CO mixture gave a stable bright or light bright red colour with consistent high a^* values for all three products, irrespective of the storage temperature. The initial level of residual O_2, up to 0.5%, did not adversely affect the visual scores and instrumental values for the colour of meat stored in the CO mixture.

CO binds to myoglobin and forms cherry red carboxymyoglobin (El-Badawi et al., 1964). This pigment is spectrally similar to the bright red oxymyoglobin which normally develops at the surface of fresh meat in air. Carboxymyoglobin is less readily oxidized to brown metmyoglobin than is oxymyoglobin, because of the strong binding of CO to the iron-porphyrin site on the myoglobin molecule (Lanier, Carpenter, Toledo, & Reagan, 1978; Wolfe, 1980). Consequently, CO in concentrations of 0.5–2.0% enhances and stabilizes a bright red colour of meat (Kropf, 1980; Sørheim et al., 1997a). In a recent study, 1% CO in combination with 24 or 70% O_2 stabilized the colour of beef by reduced formation of metmyoglobin after storage at 1°C for up to 29 days (Luño et al., 1998). However, in a study of beef stored in a MA of 2% CO/78% CO_2/20% N_2, the colour of the meat was characterized as "too artificial" by

a sensory panel (Renerre & Labadie, 1993). From our studies and experience from the Norwegian meat industry, 0.4% CO seems sufficient to produce a stable, attractive, bright red colour of meat.

All three meat types stored in high O_2 were bright red to red with high a^* values early in the storage periods, approaching the colour of meat in the CO mixture. As the microbiological counts of meat in high O_2 increased, the colour deteriorated, faster at 8 than at 4°C. Meat stored in a MA of high O_2 develops a thicker layer of oxymyoglobin than meat stored in air (Renerre & Labadie, 1993). However, the oxymyoglobin gradually oxidizes to metmyoglobin, and the oxidation is faster at higher temperatures.

For cut bone, haemoglobin released from disrupted red blood cells in the marrow will accumulate at the surface and ultimately become black after the bone has been exposed to air or O_2 (Gill, 1996). Although bone blackening was not considered in the present visual colour evaluation, it can negatively affect the saleability of bone-in meat at retail display. The cut bones of pork chops stored in high O_2 blackened during storage, but this discoloration was not observed on bones in the CO mixture and the mixture with O_2 absorbers.

Beef loin steaks stored in vacuum packs were slightly discoloured with low a^* values at both 4 and 8°C. In these packs, meat juices were observed between the upper and lower films, but that did not influence the colour evaluations.

O_2 absorbers in packs with high CO_2 facilitate the removal of residual O_2 and maintain atmospheres free of O_2 during storage (Smith, Abe, & Hoshino, 1995). Low levels of residual O_2, above 0.01–0.15% for beef and 0.5–1.0% for pork, will inevitably discolour the meat (Penney & Bell, 1993; Gill, 1996; Sørheim et al., 1997b). When no CO is present in an O_2 depleted MA, it is essential to remove the residual O_2 as fast and completely as possible to avoid formation of metmyoglobin. In these experiments, pork chops stored in the gas mixture with O_2 absorbers were moderately discoloured during the whole storage period at 4 or 8°C. Despite the obvious visible differences, these chops had similar a^* values to the chops in high O_2. The discoloured surface made the chops unfit for sale, even in the early stage of storage. The present findings contrast with previous results, where the colour of porcine *m. longissimus thoracis et lumborum* was significantly improved by using O_2 absorbers in MAs of CO_2 with residual O_2 (Sørheim et al., 1997b). The present discoloration could be caused by incomplete use or function of the absorbers (Gill, 1996).

4.3. Benefits and disadvantages of a MA with low CO/high CO_2

An objection raised against using CO as a small component of a MA for retail-ready meat is the possibility that the colour stability can exceed the microbiological shelf life, with the risk of masking spoilage of the meat (Kropf, 1980). Therefore, the consumer must evaluate the microbiological condition of meat in a CO mixture by off-odours. When a MA with CO is applied commercially, it is important to have a proper control of the hygienic condition of the meat raw materials and the chill chain temperatures.

CO used in concentrations below 1.0% does not present any hazard to the consumer, because consumption of meat packaged in such concentrations of CO will result in only negligible levels of carboxyhaemoglobin in the blood of consumers (Sørheim et al., 1997a). By delivering CO in a 1% mixture with 99% N_2, which is the practice of Norwegian gas suppliers, CO is considered safe for use in the working environment. Other MAs with high levels of O_2, up to 70%, must be regarded as explosive gas mixtures, which must be used with appropriate precautions for safety (Luño et al., 1998).

The suitability of gas mixtures and packaging methods for red meats for retail display depends on their ability to both reduce spoilage and stabilize colour. Gas mixtures with low concentrations of CO and high concentrations of CO_2 provide a combination of a long microbiological shelf life and a stable, bright red colour of meat. Meat packaged in a MA with high O_2 can achieve an initial bright red colour, but the microbiological shelf life and the colour stability are both considerably lower than those of meat in the CO mixture. Using CO eliminates the need to have O_2 as a component of the MA. Other MAs and packaging methods, like high CO_2 with O_2 absorbers, chub packs and vacuum packs may give a shelf life comparable to that of the CO mixture, but with a less acceptable colour or appearance of the meat. Thus, there appears at present to be no fully satisfactory alternative to the CO mixture used in packaging of retail-ready red meats in Norway.

Acknowledgements

The financial support of this study from the Research Council of Norway is highly appreciated. Vestfold-Buskerud Slakteri A/L, Sem and Hydrogas AS Utviklingssenter, Porsgrunn, are greatly thanked for packaging of the meat. We appreciate the gift of Ageless® O_2 absorbers from Cryovac Europe, Norderstedt, Germany. The technical staff and Per Lea (statistics) at MATFORSK are thanked for their skilful assistance in the study.

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MEMORANDUM OF CONFERENCE

May 23, 1962

BETWEEN: Mr. Donald W. Thomas, Legal Counsel, The Whirlpool Corporation
Benton Harbor, Michigan

and

Mr. A. T. Spiher, Jr., Food Additive Petitions Control Branch

SUBJECT: Combustion product gas.
Food Additive Petition 751.

Mr. Thomas called without previous appointment to discuss the above petition. He said that he had received my letter of May 10, 1962, in which we filed the petition, and said that we may need additional data on meat. These data would be needed to establish that the treatment of meat would not serve to cause the meat to retain its fresh red color longer than meat not so treated.

I explained to Mr. Thomas the way in which petitions are handled, and explained the question which we have concerning possible deception of the consumer where treatment of the meat leads to longer retention of the fresh red color. I said that they could either submit additional data on this point or they could request withdrawal of the portion of the petition for meat, and explained the different courses of action.

Mr. Thomas said that they had data concerning the retention of red color in meat, and they will get it together. He was concerned, however, about whether he should submit this as an amendment which would start the time clock over, or should withdraw animal products from the petition, to submit later on.

I said that this was a decision which he would have to make in the light of the explanation we had given him, and I suggested that he submit the data which they have and let us look at it before they did anything additional, because what they had done might be sufficient for our people.

I further suggested that when he submit the information for meat, he should supplement the data in the petition to explain exactly how the combustion product gas is to be used on the various commodities named in their petition. He said that he would do so. Briefly, he said that the gas was to be used as the atmosphere in a cold storage room.

In response to a question, he said that they had tested the effluent from their generator and were satisfied that the gas complied with the requirements established in the food additive regulation.

cc: FA DF DP BE DOM DPS

Whirlpool
CORPORATION

ADMINISTRATIVE CENTER • BENTON HARBOR, MICHIGAN

July 23, 1962

Mr. Alan T. Spiher, Jr.
Food and Drug Administration
Department of Health, Education and Welfare
Washington 25, D. C.

Subject: Food Additive Petition No. 751 FA 3/9/62

Dear Mr. Spiher:

We are in receipt of your letter of May 10, 1962, advising us of the filing of Food Additive Petition No. 751 with an effective filing date of March 24, 1962.

In view of your comments in the above-mentioned letter, we now request that our petition as originally presented be amended so as to delete any reference to animal products wherein paragraph 121.1060, section (c) of Part 121, Sub-Part D of Title 21 would now read as follows:

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, wine, fruit and fruit products and vegetable and vegetable products.

The following comments are submitted to further supplement the Remarks section of our first letter of March 6, 1962.

In food studies conducted at the Whirlpool Research Laboratories involving the use of combustion product gas as set forth in paragraph 121.1060 of Title 21, fruits and vegetables were stored under refrigeration at temperatures between

FAP3

32° and 45° F. and in their normal distribution containers, that is, baskets, crates and boxes. Products so stored had a shelf life of from three to five times that of air-stored food held at the same temperature. The results of one such study involving apples stored in air versus apples stored in conventional controlled atmosphere versus apples stored in combustion product gas are presented in the attached table. It will be noted that apples stored in combustion product gas had firmer flesh and a lower incidence of scald than did apples stored either in air or conventional controlled atmosphere even though the apples in combustion product gas were in storage for a longer period of time.

The combustion product gas under study at Whirlpool would most likely be used in the following general areas:

1. Fresh fruit and vegetable storage
2. Processors - storage, packaging and processing
3. Transportation

Because of these diverse applications, our petition requests approval for fruit and vegetable "products" as well as the natural, original raw fruits and vegetables.

To expand on the use of combustion product gas by food processors, the following examples are presented:

1. Storage of fruits and vegetables in order to have better quality control, improve yield and extend packaging season.
2. Packaging of processed foods in inert gases, i. e., nitrogen and/or carbon dioxide to prevent oxidative changes that may develop during storage.
3. Use of gas mixtures in certain processing steps as a "blanket" to keep out oxygen and prevent the associated undesirable changes.

We are hopeful that the requested amendment to the petition as well as the supplemental information presented above will clear up any questions concerning Food Additive Petition No. 751 and that favorable action will be shortly forthcoming.

Very truly yours,

WHIRLPOOL CORPORATION

By Alvin E. Mahaffay
Vice President

Color Atlas & Textbook of Hematology
Wm Platt 2nd Ed 1979

bolic pool, to be used again in protein synthesis or serve as a source of energy. Verdohemoglobin is reduced at the γ methene bridge to yield free bilirubin (orange-red, insoluble, and nonfilterable by the kidneys), which passes out of the reticuloendothelial cells into the plasma, where it is loosely bound to albumin. This bilirubin-albumin complex is carried to the liver, where it is conjugated with glucuronic acid within the liver cells. Normally most of this soluble bilirubin-diglucuronide passes into the biliary canaliculi. A small amount of this soluble, conjugated bilirubin is regurgitated back into the plasma, where it is again loosely attached to albumin. Because it is insoluble, it cannot be filtered readily by the kidneys.

From the biliary canaliculi, most of the soluble bilirubin-diglucuronide passes into the common bile duct and thence into the intestinal tract, where the bacterial flora removes the glucuronic acid, leaving the free bilirubin to be reduced in accordance with the type of bacterial flora present. One of the reduction products is urobilinogen, a colorless complex consisting mostly of stercobilinogen. When broad-spectrum antibiotics are given to patients, the bacterial flora is markedly diminished. This decreases the amount of bilirubin reduced to urobilinogen, and therefore urobilinogen excretion is reduced. Bilirubin thereby becomes the main bile pigment found in the feces. After the patient is taken off these antibiotics, the bacterial flora gradually returns, first reducing bilirubin to d-urobilinogen and then to stercobilinogen predominantly. A small amount of intestinal tract urobilinogen complex is reabsorbed and excreted again through the liver, or it appears in the urine. When feces and urine are exposed to air, they are oxidized to the urobilin group of compounds.

HEMOGLOBIN COMPOUNDS

The main function of hemoglobin in body metabolism is as a respiratory pigment in the form of oxyhemoglobin (scarlet red). As erythrocytes flow along in single file in the delicate alveolar capillaries of the lung, the partial pressure (100 torr.) of oxygen in the alveolar air converts almost all the hemoglobin in these red blood cells to oxyhemoglobin, by a process of diffusion through the erythrocyte membrane. Because the association of oxygen and hemoglobin is loose and unstable, the oxygen readily diffuses back to the tissues for oxidative purposes, and the oxyhemoglobin then becomes reduced hemoglobin (dark red). There is, then, a concomitant release of base, which binds part of the incoming carbon dioxide. Carbon dioxide is also bound as a carbamate at the free amino groups of the hemoglobin molecule. A most important portion of the carbon dioxide diffuses from the plasma into the red blood cells, where catalysis by carbonic anhydrase joins it with water to form carbonic acid, which in turn dissociates into $(H)^+$ and $(HCO_3)^-$.

Carboxyhemoglobin is one of the abnormal hemoglobin pigments incapable of carrying oxygen. It is formed when hemoglobin in the red blood cells is exposed to carbon monoxide, which has an affinity 200 times greater for hemoglobin than oxygen does. When toxic amounts of carbon monoxide are present (from automobile exhaust fumes, for example), the blood is cherry red, and anoxia may result with subsequent death caused by irreversible tissue changes. Endogenous carbon monoxide production and subsequent respiratory excretion are related to heme degradation on a one-mole-to-one-mole basis. Since there is no other source of endogenous CO, measurement of its production rate accurately quantitates the catabolism of heme compounds, and thus also the rate of hemolysis.[25] Like oxyhemoglobin, carboxyhemoglobin is seen spectroscopically at 576 μ (Plate 8).

Methemoglobin is formed when hemoglobin in its deoxygenated state (reduced hemoglobin) is oxidized to the ferric form (iron normally exists in the ferrous state in the iron porphyrin complex of the heme portion of the hemoglobin molecule. See p.

...S-2-(ethylthio) ethyl phosphorodithioates) on the same raw agricultural commodity, the total amount of such pesticides shall not yield more residue than that permitted by the larger of the two tolerances, calculated as demeton.

2. Section 120.105 is amended by adding thereto tolerances for residues of demeton in or on sugar beet tops and sugar beets. As amended § 120.105 reads as follows:

§ 120.105 Tolerances for residues of demeton.

Tolerances for residues of demeton (a mixture of *O,O*-diethyl *O*(and *S*)-2-(ethylthio) ethyl phosphorothioates) are established as follows:

12 parts per million in or on alfalfa hay, clover hay.

5 parts per million in or on almond hulls, fresh alfalfa, fresh clover, sugar beet tops.

1.25 parts per million in or on grapes, hops.

0.75 part per million in or on almonds, apples, apricots, broccoli, brussels sprouts, cabbage, cauliflower, celery, cottonseed, grapefruit, lemons, lettuce, muskmelons, oranges, peaches, pears, peas, pecans, peppers, plums (fresh prunes), potatoes, strawberries, tomatoes, walnuts.

0.5 part per million in or on sugar beets.

0.3 part per million in or on beans.

B. The Commissioner of Food and Drugs, having evaluated the data submitted in a petition filed by Chemagro Corporation, P.O. Box 4913, Kansas City 20, Missouri, and other relevant material, has concluded that the following regulation should issue with respect to residues of the food additive demeton present in dehydrated sugar beet pulp. Such residues have been shown to occur from application of the pesticide to sugar beets under agricultural uses provided for by a concurrent regulation under section 408 of the act. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(4), 72 Stat. 1786; 21 U.S.C. 348(c)(4)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625), the food additive regulations (21 CFR Part 121) are amended by adding to Subpart C the following new section:

§ 121.221 Demeton.

A tolerance of 5 parts per million is established for residues of demeton (a mixture of *0,0*-diethyl *0*(and *S*)-2-(ethylthio)ethyl phosphorothioates) in dehydrated sugar beet pulp for livestock feed when present therein as a result of the application of the pesticide in the production of sugar beets, provided that if residues of *0,0*-diethyl *S*-2-(ethylthio) ethyl phosphorodithioate are also present, the total of both residues shall not exceed 5 parts per million.

Any person who will be adversely affected by the foregoing order may at any time prior to the thirtieth day from the date of its publication in the FEDERAL ... ng Clerk, De... on, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quantuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Secs. 408(d)(2), 409(c)(4); 68 Stat. 512, 72 Stat. 1786; 21 U.S.C. 346a(d)(2), 348(c)(4))

Dated: July 26, 1961.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 61-7270; Filed, Aug. 1, 1961; 8:50 a.m.]

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Animal Feed and Animal Feed Supplements

O,O-DIETHYL *S*-2-(ETHYLTHIO) ETHYL PHOSPHORODITHIOATE

Pursuant to sections 409 and 701 of the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (25 F.R. 8625), § 121.215 of the food additive regulations (26 F.R. 2595) is revised to read as follows:

§ 121.215 *O,O*-Diethyl *S*-2-(ethylthio) ethyl phosphorodithioate.

A tolerance of 5 parts per million is established for residues of *O,O*-diethyl *S*-2-(ethylthio) ethyl phosphorodithioate, calculated as demeton, in dehydrated sugar beet pulp for livestock feed when present therein as a result of the application of the pesticide to the growing agricultural crop, provided that, if residues of demeton are also present, the total of both residues shall not exceed 5 parts per million.

This amendment does not require notice and public procedure since it is made for the purpose of bringing § 121.215 into conformity with the pesticide regulations.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Secs. 409, 701; 52 Stat. 1055, 72 Stat. 1785; 21 U.S.C. 348, 371)

Dated: July 26, 1961.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 61-7272; Filed, Aug. 1, 1961; 8:50 a.m.]

PART 121—FOOD ADDITIVES

Subpart D—Food Additives Permitted in Food for Human Consumption

COMBUSTION PRODUCT GAS

The Commissioner of Food and Drugs, having evaluated the data submitted by the Vitagen Corporation, 354 South Spring Street, Los Angeles 13, California, and other relevant material, has concluded that the following food additive regulation should issue with respect to the food additive combustion product gas used for the displacing and removal of oxygen in processing and packing of food. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625), the food additive regulations (21 CFR 121) are amended by adding to Subpart D the following new section:

§ 121.1060 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption-type filter capable of removing possible toxic impurities through which all gas used in the treatment of food shall pass; and with suitable controls to insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food being treated.

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of citrus products, vegetable fats and vegetable oils, coffee, and wine.

(d) To assure safe use of the additive, in addition to the other information required by the act, the label or labeling of the combustion device shall bear adequate directions for use to provide a combustion product gas that complies with the limitations prescribed in paragraph (b) of this section, including instructions to assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in length, and in the range of 255 millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at

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with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1))

Dated: December 7, 1962.

GEO. P. LARRICK,
Commission of Food and Drugs.

[F.R. Doc. 62-12361; Filed, Dec. 13, 1962; 8:46 a.m.]

PART 121—FOOD ADDITIVES

Subpart D—Food Additives Permitted in Food for Human Consumption

COMBUSTION PRODUCT GAS

The Commissioner of Food and Drugs, having evaluated the data submitted in petitions filed by the Whirlpool Corporation, Benton Harbor, Michigan, and the Vitagen Corporation, 1263 Westwood Boulevard, Los Angeles, California, and other relevant material, has concluded that the food additive regulation with respect to combustion product gas should be amended as set forth below. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625), § 121.1060(c) (21 CFR 121.1060; 27 F.R. 4014) is amended to read as follows:

§ 121.1060 Combustion product gas.

* * * * *

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington 25, D.C., written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof. All documents shall be filed in quintuplicate.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(c)(1), 72 Stat. 1786; 21 U.S.C. 348(c)(1))

Dated: December 7, 1962.

GEO. P LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 62-12360; Filed, Dec. 13, 1962; 8:46 a.m.]

Title 39—POSTAL SERVICE

Chapter I—Post Office Department

PART 168—DIRECTORY OF INTERNATIONAL MAIL

Individual Country Amendments

The regulations of the Post Office Department in § 168.5 *Individual country regulations* are amended as follows:

I. In country "Bolivia", under Parcel Post, amend the item "Prohibitions" to read as follows:

Prohibitions. Firearms, daggers, blackjacks, brass knuckles, sidearms and concealable weapons.

Cigarette lighters.

Gambling devices.

Pharmaceutical and medicinal products, unless approved by the Bolivian health authorities. In case of doubt, senders should ascertain from the addressees in advance of mailing whether the medicine they desire to send will be admitted.

Articles which violate the Bolivian trademark laws.

Counterfeit or illegal currency; advertisements imitating currency or postage stamps, except for philatelic or numismatic catalogs.

Adulterated or harmful beverages or foodstuffs.

II. In country "Canada", as amended by 27 F.R. 404, 27 F.R. 10369, under Parcel Post, the item "Prohibitions" is amended by revising the sixth paragraph to include "Plumage and skins of wild birds" and by adding a new paragraph at the end thereof to prescribe regulations for importing meat. As so amended, paragraph six and the new paragraph read as follows:

Prohibitions. * * *

Commercial tags of metal. Prison-made goods being sold or intended for sale by a person or firm. Plumage and skins of wild birds.

* * * * *

Meat and meat food products, unless federally inspected and passed and marked accordingly. If intended for sale, export certification by the United States Department of Agriculture is also required. Meat or meat food product for personal use is exempt from export certification, but the addressee is required to certify to the Canadian authorities that it will not be offered for sale in Canada.

III. In country "Japan", under Parcel Post, the item "Prohibitions" is amended by revising the second paragraph to include wool samples among animal products. As so amended, the second paragraph reads as follows:

Prohibitions. * * *

The following must be accompanied by official inspection certificates showing that they are free from domestic animals' infectious disease: Meat, bones, skin, hair, feathers, horns or hoofs of hoofed animals, rabbits, or poultry, wool samples, poultry eggs for hatching; honey bees.

IV. In country "Kenya and Uganda", as amended by 27 F.R. 3738, 27 F.R. 5659, under Parcel Post, amend the tabular information immediately following the item "Air parcel rates" by striking out "Weight limit: 11 pounds", and inserting in lieu thereof "Weight limit: 22 pounds."

V. In country "Laos", as amended by 27 F.R. 8592, amend the item "Observations" where it appears both under Postal Union Mail and Parcel Post, to respectively read as follows:

Observations. The following are the only post offices in operation:

Vientiane.	Paksé.
Honeisai.	Paksong.
Luangprabang.	Khongsedoné.
Sayaboury.	Champassak.
Paksane.	Muong Kong.
Khammouane.	Saravane.
Savannakhet.	Attopeu.

* * * * *

Observations. See the item "Observations" under Postal Union Mail for post offices which are in operation.

VI. In country "Tanganyika Territory" under Parcel Post, amend the tabular information immediately following the item "Air parcel rates" by striking out "Weight limits: 11 pounds" and inserting in lieu thereof "Weight limits: 22 pounds".

VII. In country "Thailand", as amended by 27 F.R. 7022, under Parcel Post, make the following changes to show that insured parcel post service is available.

A. Amend the tabular information immediately following the item "Air parcel rates" to read as follows:

Weight limit: 22 pounds
Sealing: Insured parcels must, and ordinary parcels may be sealed
Registration: No
Insurance: Yes
Postal forms required:
1 Form 2922
1 Form 2966

B. Strike out the item "*Indemnity.* No provision." and insert in lieu thereof the following:

Insurance. The following insurance fees and limits of indemnity apply:

Limit of indemnity:	Fee, cents
Not over $10	20
From $10.01 to $25	25
From $25.01 to $50	35
From $50.01 to $100	55

Insured parcels may only be addressed to Bangkok or Dhonburi.

Print on the wrapper, near the "INSURED" endorsement and number, the amount for which the parcel is insured. This amount shall be shown in United

§ 173.350 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption-type filter capable of removing possible toxic impurities, through which all gas used in the treatment of food shall pass; and with suitable controls to insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food being treated.

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

(d) To assure safe use of the additive in addition to the other information required by the act, the label or labeling of the combustion device shall bear adequate directions for use to provide a combustion product gas that complies with the limitations prescribed in paragraph (b) of this section, including instructions to assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in length, and in the range of 255 millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at 275 millimicrons of a standard reference solution of naphthalene (National Bureau of Standards Material No. 577 or equivalent in purity) containing a concentration of 1.4 milligrams per liter in purified isooctane, measured against isooctane of the same spectral purity in 5-centimeter cells. (This absorbance will be approximately 0.30.)

Solvent. The solvent used is pure grade isooctane having an ultraviolet absorbance not to exceed 0.05 measured against distilled water as a reference. Upon passage of purified inert gas through some isooctane under the identical conditions of the test, a lowering of the absorbance value has been observed. The absorbance of isooctane to be used in this procedure shall not be more than 0.02 lower in the range 255 millimicrons to 310 millimicrons, inclusive, than that of the untreated solvent as measured in a 5-centimeter cell. If necessary to obtain the prescribed purities, the isooctane may be passed through activated silica gel.

Apparatus. To assure reproducible results, the additive is passed into the isooctane solution through a gas-absorption train consisting of the following components and necessary connections:

1. A gas flow meter with a range up to 30 liters per hour provided with a constant differential relay or other device to maintain a constant flow rate independent of the input pressure.

2. An absorption apparatus consisting of an inlet gas dispersion tube inserted to the bottom of a covered cylindrical vessel with a suitable outlet on the vessel for effluent gas. The dimensions and arrangement of tube and vessel are such that the inlet tube introduces the gas at a point not above 5¼ inches below the surface of the solvent through a sintered glass outlet. The dimensions of the vessel are such, and both inlet and vessel are so designed, that the gas can be bubbled through 60 milliliters of isooctane solvent at a rate up to 30 liters per hour without mechanical loss of solvent. The level corresponding to 60 milliliters should be marked on the vessel.

3. A cooling bath containing crushed ice and water to permit immersion of the absorption vessel at least to the solvent level mark.

Caution. The various parts of the absorption train must be connected by gas-tight tubing and joints composed of materials which will neither remove components from nor add components to the gas stream. The gas source is connected in series to the flow-rate device, the flow meter, and the absorption apparatus in that order. Ventilation should be provided for the effluent gases which may contain carbon monoxide.

Sampling procedure. Immerse the gas-absorption apparatus containing 60 milliliters of isooctane in the coolant bath so that the solvent is completely immersed. Cool for at least 15 minutes and then pass 120 liters of the test gas through the absorption train at a rate of 30 liters per hour or less. Maintain the coolant bath at 0 °C throughout. Remove the absorption vessel from the bath, disconnect, and warm to room temperature.

Add isooctane to bring the contents of the absorption vessel to 60 milliliters, and mix. Determine the absorbance of the solution in the 5-centimeter cell in the range 255 millimicrons to 310 millimicrons, inclusive, compared to isooctane. The absorbance of the solution of combustion product gas shall not exceed that of the isooctane solvent at any wavelength in the specified range by more than one-third of the standard reference absorbance.

§ 173.355 Dichlorodifluoromethane.

The food additive dichlorodifluoromethane may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a purity of not less than 99.97 percent.

(b) It is used or intended for use, in accordance with good manufacturing practice, as a direct-contact freezing agent for foods.

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, dichlorodifluoromethane, with or without the parenthetical name "Food Freezant 12".

(ii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme preparations in accordance with the following conditions:

(a) The materials consist of one or more of the following:

(1) Substances generally recognized as safe in food.

(2) Substances identified in this subparagraph and subject to such limitations as are provided:

Substances	Limitations
Acrylamide-acrylic acid resin: Complying with § 173.5(a)(1) and (b) of this chapter.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Cellulose triacetate	May be used as a fixing material in the immobilization of lactase for use in reducing the lactose content of milk.
Diethylaminoethyl-cellulose	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Dimethylamine-epichlorohydrin resin: Complying with § 173.60(a) and (b) of this chapter.	May be used as a fixing material in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup, in accordance with § 184.1372 of this chapter.
Glutaraldehyde	Do.
Periodic acid (CAS Reg. No. 10450–60–9)..	

(b) They are added in an amount not in excess of that reasonably required to inhibit foaming.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 2872, Jan. 20, 1978; 46 FR 30493, June 9, 1981; 46 FR 57476, Nov. 24, 1981; 60 FR 54036, Oct. 19, 1995; 61 FR 632, Jan. 9, 1996; 63 FR 29134, May 28, 1998]

§ 173.342 Chlorofluorocarbon 113 and perfluorohexane.

A mixture of 99 percent chlorofluorocarbon 113 (1,1,2-trichloro-1,2,2-trifluoroethane) (CAS Reg. No. 76–13–1, also known as fluorocarbon 113, CFC 113 and FC 113) and 1 percent perfluorohexane (CAS Reg. No. 355–42–0) may be safely used in accordance with the following prescribed conditions:

(a) The additive chlorofluorocarbon 113 has a purity of not less than 99.99 percent.

(b) The additive mixture is intended for use to quickly cool or crust-freeze chickens sealed in intact bags composed of substances regulated in parts 174, 175, 177, 178, and § 179.45 of this chapter and conforming to any limitations or specifications in such regulations.

[55 FR 8913, Mar. 9, 1990]

§ 173.345 Chloropentafluoroethane.

The food additive chloropentafluoroethane may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive has a purity of not less than 99.97 percent, and contains not more than 200 parts per million saturated fluoro compounds and 10 parts per million unsaturated fluoro compounds as impurities.

(b) The additive is used or intended for use alone or with one or more of the following substances: Carbon dioxide, nitrous oxide, propane, and octafluorocyclobutane complying with § 173.360, as an aerating agent for foamed or sprayed food products, with any propellant effect being incidental and no more than is minimally necessary to achieve the aerating function, except that use is not permitted for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive

(1) The label of the food additive container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, chloropentafluoroethane.

(ii) The percentage of the additive present in the case of a mixture.

(iii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[42 FR 14526, Mar. 15, 1977, as amended at 43 FR 11317, Mar. 17, 1978; 43 FR 14644, Apr. 7, 1978]

§ 173.350 Combustion product gas.

The food additive combustion product gas may be safely used in the processing and packaging of the foods designated in paragraph (c) of this section for the purpose of removing and displacing oxygen in accordance with the following prescribed conditions:

(a) The food additive is manufactured by the controlled combustion in air of butane, propane, or natural gas. The combustion equipment shall be provided with an absorption-type filter capable of removing possible toxic impurities, through which all gas used in the treatment of food shall pass; and with suitable controls to insure that any combustion products failing to meet the specifications provided in this section will be prevented from reaching the food being treated.

(b) The food additive meets the following specifications:

(1) Carbon monoxide content not to exceed 4.5 percent by volume.

(2) The ultraviolet absorbance in isooctane solution in the range 255 millimicrons to 310 millimicrons not to exceed one-third of the standard reference absorbance when tested as described in paragraph (e) of this section.

(c) It is used or intended for use to displace or remove oxygen in the processing, storage, or packaging of beverage products and other food, except fresh meats.

(d) To assure safe use of the additive in addition to the other information required by the act, the label or labeling of the combustion device shall bear adequate directions for use to provide a combustion product gas that complies

with the limitations prescribed in paragraph (b) of this section, including instructions to assure proper filtration.

(e) The food additive is tested for compliance with paragraph (b)(2) by the following empirical method:

Spectrophotometric measurements. All measurements are made in an ultraviolet spectrophotometer in optical cells of 5 centimeters in length, and in the range of 255 millimicrons to 310 millimicrons, under the same instrumental conditions. The standard reference absorbance is the absorbance at 275 millimicrons of a standard reference solution of naphthalene (National Bureau of Standards Material No. 577 or equivalent in purity) containing a concentration of 1.4 milligrams per liter in purified isooctane, measured against isooctane of the same spectral purity in 5-centimeter cells. (This absorbance will be approximately 0.30.)

Solvent. The solvent used is pure grade isooctane having an ultraviolet absorbance not to exceed 0.05 measured against distilled water as a reference. Upon passage of purified inert gas through some isooctane under the identical conditions of the test, a lowering of the absorbance value has been observed. The absorbance of isooctane to be used in this procedure shall not be more than 0.02 lower in the range 255 millimicrons to 310 millimicrons, inclusive, than that of the untreated solvent as measured in a 5-centimeter cell. If necessary to obtain the prescribed purities, the isooctane may be passed through activated silica gel.

Apparatus. To assure reproducible results, the additive is passed into the isooctane solution through a gas-absorption train consisting of the following components and necessary connections:

1. A gas flow meter with a range up to 30 liters per hour provided with a constant differential relay or other device to maintain a constant flow rate independent of the input pressure.

2. An absorption apparatus consisting of an inlet gas dispersion tube inserted to the bottom of a covered cylindrical vessel with a suitable outlet on the vessel for effluent gas. The dimensions and arrangement of tube and vessel are such that the inlet tube introduces the gas at a point not above 5¼ inches below the surface of the solvent through a sintered glass outlet. The dimensions of the vessel are such, and both inlet and vessel are so designed, that the gas can be bubbled through 60 milliliters of isooctane solvent at a rate up to 30 liters per hour without mechanical loss of solvent. The level corresponding to 60 milliliters should be marked on the vessel.

3. A cooling bath containing crushed ice and water to permit immersion of the absorption vessel at least to the solvent level mark.

Caution. The various parts of the absorption train must be connected by gas-tight tubing and joints composed of materials which will neither remove components from nor add components to the gas stream. The gas source is connected in series to the flow-rate device, the flow meter, and the absorption apparatus in that order. Ventilation should be provided for the effluent gases which may contain carbon monoxide.

Sampling procedure. Immerse the gas-absorption apparatus containing 60 milliliters of isooctane in the coolant bath so that the solvent is completely immersed. Cool for at least 15 minutes and then pass 120 liters of the test gas through the absorption train at a rate of 30 liters per hour or less. Maintain the coolant bath at 0 °C throughout. Remove the absorption vessel from the bath, disconnect, and warm to room temperature. Add isooctane to bring the contents of the absorption vessel to 60 milliliters, and mix. Determine the absorbance of the solution in the 5-centimeter cell in the range 255 millimicrons to 310 millimicrons, inclusive, compared to isooctane. The absorbance of the solution of combustion product gas shall not exceed that of the isooctane solvent at any wavelength in the specified range by more than one-third of the standard reference absorbance.

§ 173.355 Dichlorodifluoromethane.

The food additive dichlorodifluoromethane may be safely used in food in accordance with the following prescribed conditions:

(a) The additive has a purity of not less than 99.97 percent.

(b) It is used or intended for use, in accordance with good manufacturing practice, as a direct-contact freezing agent for foods.

(c) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive, dichlorodifluoromethane, with or without the parenthetical name "Food Freezant 12".

(ii) The designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

§ 173.357 Materials used as fixing agents in the immobilization of enzyme preparations.

Fixing agents may be safely used in the immobilization of enzyme preparations in accordance with the following conditions:

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

Eric Greenberg
Ungaretti and Harris
3500 Three First National Plaza
Chicago, IL, 60602-4405

Re: GRAS Notice No. GRN 000083

Dear Mr. Greenberg:

The Food and Drug Administration (FDA) is responding to the notice, dated August 29, 2001, that Ungaretti and Harris submitted on behalf of Pactiv Corporation (Pactiv) in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received the notice on September 4, 2001, and designated it as GRAS Notice No. GRN 000083.

The subject of the notice is carbon monoxide (CO). The notice informs FDA of the view of Pactiv Corporation (Pactiv) that CO is GRAS, through scientific procedures, for use as a component of a gas mixture in a modified atmosphere packaging (MAP) system. The level of CO in this MAP system is 0.4 percent. The other components of the MAP system are carbon dioxide (30 percent) and nitrogen (69.6 percent). The MAP system would be used for packaging fresh cuts of case ready muscle meat and ground case ready meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat. The case ready meats would be removed from the MAP system prior to retail display.

As part of its notice, Pactiv includes letters from a panel of individuals (Pactiv's GRAS panel) who evaluated the data and information that are the basis for Pactiv's GRAS determination. Pactiv considers the members of its GRAS panel to be qualified by scientific training and experience to evaluate the safety of substances added to food. Pactiv's GRAS panel evaluated information and data on the chemical identity, manufacture and processing, conditions of proposed use, and estimated daily intakes of CO used in a MAP system for meat. Pactiv's GRAS panel also evaluated studies (published and unpublished) of the effects of CO used in a MAP system for meat. Members of the GRAS panel reviewed and evaluated the publicly available information summarized in the GRAS notice. Based on the data and information reviewed, Pactiv's GRAS panel concludes that CO, when produced in accordance with current good manufacturing practice and meeting appropriate food grade specifications, is GRAS, through scientific procedures under the conditions of its intended use.

The notice describes publicly available information pertaining to the identity and characteristic properties of CO. Carbon monoxide (Chemical Abstracts Service Registry Number 630-08-0) is a colorless, odorless, gas. The notice includes a list of properties of CO and identifies the

manufacturer who currently supplies CO to Pactiv. Pactiv intends to use CO at a minimum purity of 99.99 percent ("commercial grade"). Pactiv includes a list of specifications for CO with limits on the levels of other gases and considers CO of this purity to be "food grade."

The notice describes information about existing regulations and notices regarding food substances that contain CO as a significant component:

- Wood smoke, which includes CO as a component, is permitted by regulation as an ingredient in meat and poultry products under regulations issued by the U.S. Department of Agriculture (9 CFR 318.7(c)(4), 381.147(c)(4) and 424.21(c)).

- Combustion product gas, which includes CO as a component at a maximum level of 4.5 percent by volume, is approved for use in the production of beverages and other foods (except fresh meat) under FDA's regulations (21 CFR 173.350).

- Tasteless smoke, which includes CO as a primary component, is the subject of GRN 000015 for use on raw tuna, before it is frozen, to preserve its taste, aroma, texture, and color. In response to GRN 000015, FDA had no questions regarding the notifier's conclusion that tasteless smoke is GRAS under the intended conditions of use.

The notice describes the estimated consumption of CO per meal as a consequence of its intended use as a component in a MAP system for storing meat. Assuming that 30 percent of the CO present in the MAP is absorbed into the meat and that there is an 85 percent reduction of CO due to cooking the meat, Pactiv calculates a realistic intake estimate to be 0.084 milligrams (mg) CO per meal. Pactiv also calculates a worst case intake estimate to be 1.88 mg CO per meal, assuming that 100 percent of the CO present in the MAP is absorbed into the meat and that there is no reduction in CO during cooking. Pactiv cites published articles to support the assumptions used in the realistic exposure estimate and to support the conclusion that exposure to CO is safe at this level.

The notice describes published reports of studies demonstrating the technical effect and safety of using CO as a component of a MAP system (similar to the MAP system that is the subject of GRN 000083) for storing meat. These reports include published data (microbial growth profiles and odor and color data) from meat stored in MAP containing CO, CO_2, and N_2, and meat stored in MAP containing only CO_2 and N_2. Pactiv concludes that the presence of CO in MAP systems allows the meat to maintain a desirable red color during storage. In addition, CO neither affects the ability of the MAP system to slow the growth of a variety of microorganisms, nor affects the characteristic odor of meat spoilage.

The notice describes an unpublished study using the MAP system that is the subject of GRN 000083. The study examined the effects of the system on initial meat color, stability of color during display, and the relationship between color deterioration and microbial growth. The notice also includes unpublished pictures that compare the ageing (color deterioration) of meats stored for 20 days in an environment of CO, CO_2, and N_2, to the ageing of fresh cut meat and the ageing of meat stored in a high oxygen environment. From these data, Pactiv concludes that once meat is removed from a MAP system containing CO, its color deteriorates at a similar rate to

that of meat that has not been exposed to CO. Pactiv also concludes that the use of CO in a MAP system does not result in red color life extension that could mask microbial spoilage of the meat.

Based on the information provided by Pactiv, as well as other information available to FDA, the agency has no questions at this time regarding Pactiv's conclusion that CO is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of CO. As always, it is the continuing responsibility of Pactiv to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

During its evaluation of GRN 000083, OFAS consulted with the Labeling and Consumer Protection Staff of the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture regarding the use of CO in meat products. Based on the information submitted by Pactiv, FSIS has concluded that the MAP system (ActiveTech™ 2001) as described in Pactiv's notice, and used under the conditions stated in Pactiv's notice, would be acceptable for packaging red meat cuts and ground meat. In FSIS' view, Pactiv has demonstrated that this MAP system complies with FDA's definition of a processing aid that appears in labeling regulations (21 CFR 101.100(a)(3)). There is no lasting functional effect in the food and there is an insignificant amount of carbon monoxide present in the finished product under the proposed conditions of use. As such, similar to uses of other MAP gases (e.g., nitrogen), there are no labeling issues in regard to meat cuts and ground meat packaged using this MAP. Additionally, when considering the use of a food ingredient or additive in a meat product, FSIS historically has treated each livestock species separately. However, in this case, the data submitted by Pactiv can be extrapolated to all species of livestock. If you have any additional questions, you should direct your inquiry to Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, 300 12th Street, SW, Room 602, Washington, DC 20250-3700. The telephone number of his office is (202) 205-0279 and the FAX number is (202)205-3625.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,

Alan M. Rulis

Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

United States Department of Agriculture

Food Safety and Inspection Service

Office of Policy, Program and Employee Development

Washington, D.C. 20250/3700

Mr. Ralph Simmons
Keller and Heckman, LLP
1001 G Street NW
Suite 500 West
Washington, DC 20001

FEB 5 2003

Dear Mr. Simmons:

I am responding to your request of December 11, 2002, on behalf of your client, Cryovac North America (Cryovac). On November 15, 2002, Cryovac requested that the Food Safety and Inspection Service (FSIS) review the acceptability of its low oxygen case ready modified atmosphere packaging (MAP) system that incorporates carbon monoxide (CO) to maintain wholesomeness. In response to the information that you and your client provided, FSIS informed Cryovac in a letter dated December 19, 2002, that FSIS would need to consult with the Food and Drug Administration (FDA) to request their interpretation on whether Cryovac's use of CO in their MAP system is consistent with GRAS Notice No. GRN 000083.

FDA responded in writing to our request on January 27, 2003, in which they conveyed that the use of CO in Cryovac's MAP system is generally recognized as safe (GRAS). Specifically, Cryovac's MAP is similar to the MAP system in GRAS Notice No. GRN 000083, i.e., the MAP uses the same concentrations of carbon dioxide, nitrogen, and CO, except that the physical packaging system is slightly different. However, because Cryovac's container has a tab that is removed at the point of sale to allow the CO to escape from the package, the atmosphere within the package can equilibrate with the standard atmosphere outside the package. This change in the atmosphere within the package will allow the meat pigment color to change over time as though it had not been exposed to CO. As a result, FDA concluded that Cryovac's MAP system fell within the scope of GRAS Notice No. GRN 000083.

Because Cryovac's use of CO in their MAP system is consistent with GRAS Notice No. GRN 000083, FSIS does not object to the use of this MAP system to package case ready fresh meat. If you have any additional questions, please contact Mr. Jeff Canavan, Food Technologist, at Area Code (202) 205.0279.

Sincerely,

Sally L Jones

Robert C. Post, Ph.D., Director
Labeling and Consumer Protection Staff